

The Orphan Drug Act: An Unconstitutional Exercise of the Patent Power

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I. INTRODUCTION

In 1983, Congress adopted the Orphan Drug Act (the "Act") pursuant to its power to regulate interstate and foreign commerce to stimulate research and development of drugs useful in treating relatively rare diseases.¹ The cost of drug research and complying with the complex requirements for securing governmental approval to market drugs left many illnesses "orphans."² "Ratio-

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1. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. §§ 360aa-360ee (1988)). The legislative history of the Act is thoroughly traced in David M. Richardson, *The Orphan Drug Tax Credit: An Inadequate Response to an Ill-Defined Problem*, 6 AM. J. TAX POL'Y 135, 138-68 (1987).

2. The process for securing marketing approval for new drugs in the United States is complex and expensive. After engaging in research to develop a new drug, a drug manufacturer must then engage in pharmacological and toxicological investigations to determine the drug's characteristics. Next, Food and Drug Administration ("FDA") approval for clinical testing must be secured through the process of applying for an Investigational New Drug exemption from the Food Drug and Cosmetic Act, 21 U.S.C. § 355 (1988), a procedure designed to insure that the health and safety of human subjects in the clinical testing are protected. Three phases to the clinical trials must usually be followed. Phase 1 serves to develop data on side effects and relative effectiveness; Phase 2 is designed to evaluate the effectiveness of the drug for a particular disease or condition; and Phase 3 is designed to establish safety and effectiveness information in order to make an overall risk-benefit judgment concerning the drug and to provide labelling information. The entire process may take several years and cost millions of dollars. See Li-Hsien Rin-Laures & Diane Janofsky, *Recent Developments Concerning the Orphan Drug Act*, 4 HARV. J.L. & TECH. 269, 271-72 (1991); Cynthia A. Thomas, *Re-Assessing the Orphan Drug Act*, 23 COLUM. J.L. & SOC. PROBS. 413, 420-21 (1990) ("It presently takes approximately ten years and an average of \$97 million to develop and market a drug.")

The accuracy of estimates of the average total cost from research and discovery to FDA approval is questionable because of widely varying estimates and the growing practice of expediting the drug approval process for drugs useful in treating terminal or chronic illnesses. Expedited approval processes have been used in the case of Orphan Drugs. In the past, the process for gaining approval was long and expensive. One study

nally maximizing" drug manufacturers did not care about the illness from a research and marketing viewpoint because of the lack of sufficient economic incentives to engage in research and undertake the governmental approval process for marketing safe and effective drugs to treat "orphaned" diseases.³ Between ten and twenty million Americans suffer from one of approximately 5,000 rare diseases and could benefit from research, development, and marketing of drugs useful in treating rare diseases.⁴ Congress chose to remedy the twin problems of inducing research into drugs having a relatively thin market potential and overcoming the costs of securing Food and Drug Administration (FDA) approval for marketing the drug through the Orphan Drug Act by providing drug researchers and manufacturers a series of incentives, including: (1) federal funding of grants and contracts for clinical testing of Orphan treatments;⁵ (2) a tax credit of 50% of the costs of clinical testing;⁶ (3) the creation of the Orphan Product Board

for 1967, showed Phase 1 clinical studies lasted an average of 9.1 months at an average cost of \$166,000 in 1967 dollars; Phase 2 studies lasted an average of 23.2 months at an average cost of \$881,000 in 1967 dollars; and Phase 3 studies lasted an average of 33.6 months at an average cost of \$1,546,000 in 1967 dollars. See Ronald L. Desrosiers, Note, *The Drug Patent Term: Longtime Battleground in the Control of Health Care Costs*, 24 NEW ENG. L. REV. 115, 121 (1989).

3. It has been pointed out that the Act addressed an unintended and undesirable effect of this country's drug approval process—the lack of economic incentives for developing drugs sorely needed by those afflicted with rare diseases. The price we as a nation pay for a quality drug approval system that only permits marketing of demonstrably safe and effective drugs is extraordinarily high developmental costs. When developmental costs cannot be recovered and profits are unlikely, drugs are not developed.

Patricia J. Kenney, *The Orphan Drug Act—Is it a Barrier to Innovation? Does It Create Unintended Windfalls?*, 43 FOOD DRUG COSM. L.J. 667, 667 (1988).

4. U.S. DEPT OF HEALTH AND HUMAN SERVICES, REPORT OF THE NATIONAL COMMISSION ON ORPHAN DISEASES xiii (1989) [hereinafter REPORT].

5. 21 U.S.C. § 360ee provides the following authority:

- (a) Authority of Secretary

The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the costs of qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions.

21 U.S.C. § 360ee (1988). Subsection (c) appropriates \$10 million for 1988, \$12 million for 1989 and \$14 million for 1990 to support grants and contracts authorized under subsection (a). *Id.* § 360ee(1).

6. 26 U.S.C. § 28 (1988); see also 26 C.F.R. § 602 (1991).

to coordinate and facilitate the development of orphan drugs;⁷ and (4) the grant of an exclusive right to market an orphan drug for seven years to the first applicant receiving FDA marketing approval of the drug for the designated orphan disease.⁸

Originally, Congress limited the availability of the Act to drugs for diseases where there was "no reasonable expectation that the cost of developing and making available" the drug in the United States could be recovered from sales in the United States.⁹ This standard soon proved unworkable because it necessitated complex proof that the drug would in fact be unprofitable. Congress responded in 1984 by defining "rare diseases" as those with patient populations of less than 200,000 in the United States; in cases where the patient population may exceed 200,000, Orphan Drug status may be gained where one can prove that a drug is not expected to cover the costs of bringing it to market.¹⁰ While

7. 42 U.S.C. § 236 (1988).

8. 21 U.S.C. § 360cc (1988). This section provides that the Secretary may not approve another application or issue a certificate or license for "such drug for such disease or condition . . . until the expiration of seven years from the date of the approval of the approved application, the issuance of the certification, or the issuance of the license." *Id.*

This section of the Act also enumerates two instances in which the Secretary may issue certificates or licenses to others. The first is where "the holder of the approved application, of such certification, or of the license cannot assure availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated." The second is where the holder of the certification or license consents in writing to the certification or licensing of other applicants. *Id.*

Proposed Orphan Drug Regulations, 56 Fed. Reg. 3338 (1991) (to be codified at 21 C.F.R. § 316) (proposed January 29, 1991), emphasizes the exclusive nature of the grant by providing:

FDA interprets the act to accord exclusive approval only to the first drug approved. This interpretation means that other applicants, who may have invested substantial money and effort in supporting their applications, are barred from marketing for the 7 year period of exclusivity even though they filed before or shortly after the applicant whose product was approved. . . .

FDA is required by law to reject the concept of joint or shared exclusivity (unless it is agreed to by all sponsors of a particular drug). *Id.* at 3341.

9. 50 Fed. Reg. 19,583 (1985); see also Thomas, *supra* note 2, at 416.

10. 21 U.S.C. § 360bb(2) (1988). Subsection (2) of that section provides in its entirety:

(2) For purposes of paragraph (1), the term "rare disease or condition" means any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to

removing the source of ambiguity concerning the definition of an "Orphan Drug,"¹¹ the amendment created other ambiguities. For example, where the drug is useful in a patient population under 200,000, Orphan Drug status is fixed at the time of designation and is not reviewed thereafter.¹² Consequently, a particular illness like AIDS may meet the objective numerical test at the time of designation for Orphan Drug exclusivity, but then rapidly outgrow the numerical test during the seven year period of market exclusivity and be highly profitable as a result.¹³

Amendments passed by Congress in 1990,¹⁴ and pocket vetoed by President Bush, would have caused exclusivity to be revoked where the patient population exceeded 200,000 during the seven-year term and provided for shared exclusivity where the drug appeared profitable from the beginning. In a "Memorandum of Disapproval" explaining the pocket veto, Bush stated that revoking the status would weaken market incentives created by the Act by sending "a troublesome signal" to developers of Orphan Drugs by retroactively changing the rules "for firms that made investment decisions based on the expectation of 7 years of market

any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

Id.

11. It should be noted that many illnesses most people consider common have the potential to be classified as orphan diseases dependent upon how narrow the classifications are drawn. It has been stated that "the Orphan Drug Act classifies as orphan diseases such ailments as asthma, anorexia, AIDS, colitis, glaucoma, heart disease, hemophilia, hepatitis, liver disorders, chronic pain, lead poisoning, tuberculosis, leukemia and most forms of cancer, including cancer of the bladder, brain, cervix, esophagus, head and neck, lung, lymphoma, ovary, and pancreas." James R. Love, TAXPAYER ASSETS PROJECT, WORKING PAPER NO. 6, THE ORPHAN DRUG ACT AND GOVERNMENT SPONSORED MONOPOLIES FOR MARKETING PHARMACEUTICAL DRUGS (January 1992).

12. The final sentence of § 360bb expressly provides that the facts and circumstances "as of the date the request for designation . . . is made" shall govern the determination of whether the drug qualifies as an Orphan Drug. 21 U.S.C. § 360bb (1988). In its pending rule making, the FDA rejects the notion of joint licensing for simultaneous filings and the notion that competing applicants are entitled to a hearing before a license or certificate is issued. Only one applicant can be granted a license or certificate, absent the consent of certificate holder. 56 Fed. Reg. 3338, 3341 (1991) (to be codified at 21 C.F.R. § 316) (proposed Jan. 29, 1991).

13. See Thomas, *supra* note 2, at 431-32. At the time the drug AZT was designated an Orphan Drug, it was estimated that the patient population was 45,000. In 1989, the estimated patient population was 600,000. *Id.*

14. 136 CONG. REC. H5799 (daily ed. July 30, 1990).

exclusivity."¹⁵ It has been appropriately pointed out that this rationale "exaggerates" the impact of revoking the designation where the population exceeds 200,000 because few orphan diseases will grow beyond a patient population of 200,000 and the drug may still retain exclusivity where it can be shown to be unprofitable.¹⁶

A particular drug may meet more than the needs of the patient population for which it is a designated Orphan Drug and have significant sales for other and more widespread illnesses. While the FDA designates the drug for a particular illness and the holder of the designation may not openly promote its use for other illnesses, doctors may prescribe it for other illnesses where it is found useful.¹⁷ Market exclusivity for the holder of the Orphan Drug designation in such circumstances may give it an exclusive market over a broader range of illnesses than just those for the designated orphan illness.¹⁸

A further ambiguity is caused by the manner in which a particular illness is classified as an orphan disease. In what one witness before recent Congressional hearings called "salami slicing,"¹⁹ separate applications for orphan disease status can be divided up into narrow classifications and subclassifications of the same generic disease. For example, the various forms and locations of cancer are treated as separate diseases, so that a disease like ovarian cancer can be distinguished from other forms of cancer for purposes of the Act because it has an estimated population of 160,000.²⁰ It has even been possible to have the same drug independently designated an Orphan Drug for several discrete illnesses no one of which exceeds the 200,000 patient population but which gives exclusivity over sales of the drug for a

15. 137 CONG. REC. H73-74 (daily ed. Jan. 3, 1991).

16. Rin-Laures & Janofsky, *supra* note 2, at 280-81.

17. Thomas, *supra* note 2, at 429-30; Rin-Laures & Janofsky, *supra* note 2, at 281-82.

18. An often cited instance of this practice is the drug Epogen, given orphan status for end-stage renal disease and chronic kidney failure. Epogen is an artificial form of erythropoietin, or EPO, a protein manufactured by the kidneys to stimulate red blood cell production. It has uses beyond the treatment of renal failure, and other companies are seeking approval of its sale for other end uses. See Thomas, *supra* note 2, at 430-31. The human growth hormone, hGH, was designated for treating hypopituitary dwarfism, but has now been found to be useful in treating other growth hormone disorders and aging in men. Rin-Laures & Janofsky, *supra* note 2, at 281.

19. Love, *supra* note 11, at 6.

20. *Id.*

combined patient population in excess of 200,000.²¹ While the letter of the law may be obeyed by such tactics, its spirit is certainly abused.²²

Finally, the measurement of less than a 200,000 patient population is expressly limited to a patient population in the United States and does not take account of potential foreign sales of the drug where a particular affliction may affect millions and generate highly profitable sales. One study concluded that thirty-six drugs eligible for orphan status at the time of the adoption of the Act had foreign markets of over one million patients.²³ While FDA action designating a drug as an orphan drug is limited to domestic sales, the designation may carry with it effective control over foreign sales as well by providing monopolized domestic market support for foreign sales.

In 1985 Congress further amended the Act by expanding its application to patented as well as non-patented drugs and extended the scope of the application of the Act to antibiotics and biologics intended for treating rare diseases.²⁴ The extension of the Act to patented drugs was believed necessary because the long approval process for many drugs meant that several years of patent protection may be lost before a patented drug may be marketed and many of the drugs having application to rare diseases were near the end of their patent term when a rare disease

21. Biogen, Inc. has been notably successful with "salami slicing." It is reported: In February 1991, FDA granted the firm orphan drug status for its drug r-IFN-beta to be used in the treatment of metastatic renal cell carcinoma. In April, the firm received orphan drug designation for the same drug in the treatment of cutaneous malignant melanoma. Fifteen days later, r-IFN-beta earned orphan drug designation for the treatment of cutaneous T-cell lymphoma. Then it received designation for AIDS-related Kaposi's sarcoma and multiple sclerosis. The combined patient population exceeds the 200,000 threshold several times.

Suzanne Tregarthen, *Prescription To Stop Drug Companies' Profiteering*, WALL ST. J., March 5, 1992, at A13.

22. Other complexities abound. For example, it is possible for the FDA to grant Orphan Drug status on a patented drug to a party other than the patent holder. An exclusive marketing right may be granted to an applicant taking advantage of government research or government sponsored research, thereby resulting in the public paying both for the research producing the drug and the monopoly pricing for the drug which may be charged by the holder of the Orphan Drug designation.

23. Thomas, *supra* note 2, at 429.

24. Orphan Drug Amendments of 1985, Pub. L. No. 99-91, 99 Stat. 387 (1985) (amending 21 U.S.C. § 301 (1988)).

application was discovered or applied for.²⁵ The 1985 amendment allows a form of "tacking" to take place by adding seven years of marketing exclusivity to the life of an about-to-expire patent, even though there has not been any additional disclosure of a new invention. The seven year period of Orphan Drug exclusivity runs from the time of FDA approval for marketing, unlike the seventeen year period of exclusivity for a patent which runs from the date of issue of the patent and not the date of FDA approval for marketing the patented drug.²⁶ Pharmaceutical manufacturers cite the grant of seven years marketing exclusivity as the most important incentive to Orphan Drug research and development²⁷ and it has been recommended by the National Commission on Orphan Diseases that the seven year period of exclusivity be increased.²⁸

Measured superficially in terms of the total number of new drug applications for rare or orphan diseases, the Act has been a success. It has been estimated that prior to the adoption of the Act, only ten drugs meeting the Act's standards had been approved by the FDA.²⁹ In the first seven years of the Act's life, 45 orphan drugs had been approved and 133 were undergoing clinical trials.³⁰ Even though the developer of a drug is not assured of gaining Orphan Drug status over competing applicants, the prospect of having the exclusive right to market the drug for seven years has often stimulated competition.³¹

25. *Orphan Drug Amendments of 1985, Hearings Before House Comm. on Energy and Commerce*, 99th Cong., 1st Sess. (1985); H.R. REP. NO. 99-153 (1985); see also Thomas, *supra* note 2, at 426.

26. This problem may have been remedied by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C § 301 (1988). But see Patti, *Section 202 of the Drug Price Competition and Patent Term Restoration Act—Has Congress Acted Constitutionally*, J. PAT. OFF. & TRADEMARK SOC'Y 567 (1987) (arguing the failure of the Act to grant absolute "exclusivity" to inventors violates the constitutional requirement that inventors be given the "exclusive" right to their invention). For an excellent review of the issue of the appropriate length of the "limited times" which should or should not be available for patents on drugs see Desrosiers, *supra* note 2. For a harsh criticism of the Act, see Mezrich, *The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake*, 74 J. PAT. OFF. & TRADEMARK SOC'Y 77 (1992).

27. REPORT, *supra* note 4, at 58.

28. *Id.*

29. Rin-Laures & Janofsky, *supra* note 2, at 270.

30. *Id.*

31. Kenney, *supra* note 3, at 675-77 (reviewing competition between five companies to secure an Orphan Drug designation for Human Growth Hormone (hGH)).

One can not know, short of a case-by-case examination of the confidential applications, the degree to which their gross number reflects a truly significant rise in research and development of drugs which would not otherwise have been produced save for the existence of the exclusivity incentive on top of the other generous incentives. The exclusivity conferred by the Act is a rare form of exclusivity: it is absolute, government enforced, protects against both actual and potential competition, and is not accompanied by rate regulation. Practices like "salami slicing", having the same drug applied to several different illnesses, exploiting research by government scientists or government grants, and obtaining Orphan Drug status for diseases likely to expand beyond a 200,000 patient population or which can meet the needs of large numbers in other countries, signal that profit maximizing opportunism is taking place rather than solemn and altruistic commitments by private drug manufacturers to the humanitarian goals of the Act.

In addition, the likelihood of monopoly profits from exclusive marketing rights for Orphan Drugs may well be distorting the rational allocation of research and development resources in the general drug research market is a real probability but cannot be accounted for in gross measures of the number of Orphan Drug Act applications. Stated harshly and perhaps unfairly, the gross number of Orphan Drug approvals and applications, when viewed in light of the other subsidies provided in addition to market exclusivity, does little more than confirm the generalization that profit maximization (greed) most likely drives private investment decisions to do research for Orphan Drugs. It does not justify the conclusion that but for market exclusivity, rather than other forms of incentives, we would not have seen the marked upswing in the number of Orphan Drugs being brought to market.

Not surprisingly, there has been significant controversy concerning claims that the lure of seven years of market exclusivity is generating abuses of the Act and its purpose. For example, it appears that some applications for Orphan Drug status have been intentionally drafted to meet the 200,000 patient population even though the drug can serve a far wider range of patients.³² The resulting seven years of exclusivity means that far greater

32. See Rin-Laures & Janofsky, *supra* note 2, at 288-89.

sales are being made than just those sales for the claimed orphan drug patient population and the profitability of the drug is far greater than was originally represented in the application for Orphan Drug status.

Congressional critics of the Act have reported that the prices charged for some orphan drugs are so high that they are effectively denied to orphan disease sufferers and that monopoly pricing is contributing to the escalation of health care costs and the costs of public welfare and other insurance systems paying for the drugs.³³ For example, Congressman Studds has cited the case of the Orphan Drug "Ceredase," a drug used to treat suffers of Gaucher's disease—a rare inherited disorder which deprives its victims of an enzyme which normally dissolves certain fatty material in the body.³⁴ Victims of the illness suffer great pain and die in early middle age. Ceredase replaces the missing enzyme and, although not a cure for the disease, patients taking the drug

33. Excessive profits are the most visible adverse effect of monopolies, but not the most significant long term effects of an exclusive monopoly. The adverse effects on innovation and efficiency for both research on the particular orphan disease and the production of the drug designated for its treatment are more important consequences of the grant of exclusivity. Once a market is fenced off, particularly by the government grant of an exclusive and unregulated monopoly, the incentives for further research and cost savings in producing the product for the fenced off market are eliminated. The progress of science and the useful arts gained by public disclosure of new discoveries is thought to justify fencing off the market for truly new inventions because they add to the store of human knowledge and stimulate further research based upon the disclosure of the new idea. But where there is no disclosure of a truly new invention, fencing off a market from competition only serves to deny society the benefits of further research and innovation by competitors seeking to serve the fenced off market. Where the market is closed, why should competitors and the monopolist invest in research, production, and other forms of innovation?

Paradoxically, the choice to stimulate innovation in the treatment of orphan diseases by the creation of seven years of marketing exclusivity may well be leading to the opposite long term effect, along with monopoly pricing exploiting the victims of rare diseases. As Professor Michael Porter has observed:

It is well established in economics that progressiveness or innovativeness is by far the most important source of economic growth and welfare, greatly out-weighing price/cost margins (allocative efficiency) or even static efficiency. The central focus of antitrust policy, in my view, ought to be on fostering progressiveness, defined broadly to include not only technological innovation by new ways of competing in product, marketing, service, and so on. When faced with tradeoffs, we should weigh progressiveness much higher than static efficiency or a snapshot of price-cost margins.

Innovation, Rivalry and Competitive Advantage: Interview with Professor Michael E. Porter, ANTITRUST, Spring 1991, Vol. 5, No. 2, at 5.

34. 137 CONG. REC. E2435 (June 27, 1991).

are considerably improved even though they must take treatments every two weeks for the remainder of their lives. The present average annual price for treatment is approximately \$200,000,³⁵ a price victims cannot long pay and one their insurance program may not cover or will not sustain beyond the maximum limit of their policy.³⁶ While it is not clear whether the high price for the drug is attributable to development and production costs or whether it is due to monopoly pricing by the manufacturer holding the Orphan Drug designation, or both, it is clear that the objective of stimulating development of drug treatments for rare disorders or illnesses is not worth much to those who cannot afford to pay the price.

Marketing exclusivity for a seven year period has meant the discretion to engage in monopoly pricing resulting in profits far in excess of research and FDA approval costs.³⁷ Frequently cited

35. This is a conservative estimate. In hearings on The Orphan Drug Act Amendments of 1991, a bill introduced by Senators Kassebaum and Metzenbaum ending exclusivity status when sales of an orphan drug reach \$200 million, testimony concerning "Ceredase" was said to cost one patient \$340,000 per year. *Orphan Drug Act Amendments of 1991, Hearings on S. 2060 before the Labor and Human Resources Comm.*, 102d Cong., 1st Sess. (March 3, 1992) (not yet available). Testimony by Genzyme Corp., manufacturer of "Ceredase," suggested that the high cost of the drug lasts only for the first several months of intensive drug therapy and that the patient cost would be subsequently reduced when intensive therapy ends and a lower level of drug would then be administered. *Witnesses Outline Current Abuses of Orphan Drug Act, Call for Changes*, Daily Rep. for Executives (BNA), at A10 (Jan. 22, 1992).

36. The common lifetime limit on insurance coverage is \$1,000,000 for those who have insurance coverage. 137 CONG. REC. E2435 (daily ed. June 27, 1991).

37. In the model of a pure competitive market, price is driven to marginal cost. While no market meets all the requirements for a purely competitive market, it is generally the case that competition causes price to be more or less linked to and governed by cost. In those industries characterized by natural monopoly and rate regulation, the entire exercise of rate regulation is driven toward linking "just and reasonable" rates to the cost of providing the service, including a reasonable return on investment. This does not appear to be the case with regard to the pricing of Orphan Drugs insulated from price competition for a seven year period and not presently rate regulated. Like any monopolist free to price a product above cost, the monopoly firm's pricing decisions focus on factors other than cost.

The Author recently received a newsletter from Charles River Associates ("CRA"), economic consultants, outlining their advice to a client seeking CRA's advice on the pricing of a drug newly designated as an Orphan Drug. *Fair Pricing for New Products: Orphan Drugs*, CRA REV. (Charles River Assoc., Inc., Boston, Mass., Jan. 1992) (on file with *Utah Law Review*). CRA's study of the issue listed the factors it relied upon in fashioning their advice to the unnamed client as follows:

- (1) How much money would payers save overall by covering the new therapy in lieu of alternative therapies?
- (2) What are the major constraints and opportunities in terms of reim-

examples include EPO for treating end stage renal failure,³⁸ Protropin or Human Growth Hormone for treating dwarfism,³⁹ AZT for treating AIDS,⁴⁰ and instances of Orphan Drugs in the

bursement, legislative, and market issues, and how would these factors relate to pricing the client's product?

(3) What price for the drug would be considered "fair" in relation to prices of similar therapies and traditional industry practice?

(4) What price would allow the firm to meet its revenue goals?

Id. at 2.

In developing its analysis, CRA focused on the value of the benefit received by the patient from receiving the drug, priced at \$10,000 in "economic benefit." *Id.* "Economic benefit" was measured in terms of enhanced potential wage earning, reduced demands on the time of friends and relatives in providing care, and reductions in the need for attendant care and lower direct medical costs for hospitalization and other drug therapies. *Id.* Other factors like comparable pricing practices by other drug companies and public and other expressions of concerns over the pricing of Orphan Drugs were taken account of in setting a "fair price." A reduction of 25% from the "economic benefit price" of \$10,000 was suggested in light of these factors and was adopted by the client. *Id.* at 2-3.

What is noteworthy, but not unexpected, about this description of the process for setting price is that it is pricing based on the principle of what the traffic will bear, divorced from the cost of producing the product, including regulatory compliance costs. The problem of covering costs to bring the drug to market is simply assumed and it is further assumed that the client is free to "meet its revenue goals." *Id.* at 2. It is a form of monopoly pricing discretion, one expressly sanctioned by the Act and one CRA appears to have advised its client to exercise. While it may be "fair" monopoly pricing from a cynical and tactical political point of view, it nevertheless is monopoly pricing from an economic point of view which would not occur in a competitive market or in a rate-regulated one.

38. See 137 CONG REC. E1171 (daily ed. April 10, 1991) (statement of Congressman Stark) (citing cost of EPO to Medicare of \$265 million in one year and development costs for the drug of \$170 million).

39. *Id.* (costs of \$45 million to develop the drug and sales in 1989 of \$123 million).

40. Philip J. Hilts, *Wave of Protests Developing On Profits from AIDS Drug*, N. Y. TIMES, Sept. 16, 1989, § 1, at 1. The article estimates the initial price for annual AZT treatments at \$8,000, that the costs of bringing the drug to market were between \$80 to \$180 million, and sales for one year generated \$220 million and profits of as much as \$100 million. With the increase in AIDS patients, sales are estimated to top \$1 billion by 1992. The manufacturer reduced prices in the face of protests to around \$6500 per year in 1989. Tregarthen, *supra* note 21, at A13.

It should be noted that some Orphan Drugs on which apparently exorbitant profits have been made have independent patent protection and many are the result of government funded research resulting in patented drugs with exclusive licenses to private drug manufacturers. The marketing of a particular drug may be protected from competition by one monopoly grant piled on another. Independent patent protection may be added to Orphan Drug protection from competition, or an exclusive patent license on government held patents may confer an added level of exclusivity to a drug designated an Orphan Drug. Monopoly pricing, therefore, may be due in part to patent rights, questionable extensions of the patent grant by adding Orphan Drug exclusivity protection to expiring patent protection and unwise licensing practices for federally funded research resulting in private patents or exclusive licenses of government held patents. The issue of the scope and length of drug patents is reviewed in Desrosiers, *supra* note

United States being priced up to ten times more than they are in other countries with competitive markets for the drug.⁴¹ The resulting monopoly tax upon the victims of relatively rare diseases and their public and private insurers and the contribution to spiraling health care costs have all brought repeated attempts to curb the scope of the Act—most noticeably proposals to limit or curb the seven year exclusive marketing right.⁴²

Frequently, the basis of the discovery of drugs useful in treating diseases is the product of government funded research or the research of government scientists. For example, AZT was in part the product of research by government scientists, yet Orphan Drug status for the drug has given an exclusive seven-year monopoly over distribution of the drug to a private company.⁴³ There is now litigation challenging the validity of the private company's AZT patent on the grounds that it was not the inventor.⁴⁴ The orphan drug Taxol, useful in treating ovarian and other forms of cancer, is the product of government funded research isolating Taxol from the bark of pacific yew trees nearly thirty years ago.⁴⁵ The monopoly granted over marketing Taxol has been considerably expanded by an arrangement between the National Cancer Institute and the company holding the Orphan

2, at 115. The further issue of extending the life of drug patents to compensate for delays in FDA marketing approval of patented drugs is criticized in Mezrich, *supra* note 26, *passim*.

41. Thomas states:

For example, in the United States aerosol pentamidine is an orphan drug with a monopoly that supports a retail price up to \$300 per vial. This same drug is available in Europe from a competitor for approximately \$30 per vial. The enormous price disparity is evidence that the high domestic price does not represent mere cost recovery, but is a result of the artificial monopoly. Similarly, erythropoietin, an orphan drug in the U.S., is available more cheaply in Germany and Switzerland from competitors.

Thomas, *supra* note 2, at 428; *see also* Desrosiers, *supra* note 2, at 133 (reviewing evidence which suggested that price of Valium in United States was 342% higher than in United Kingdom and 243% higher than in Canada).

42. *See, e.g.*, H.R. 5421, 101st Cong., 2d Sess. (1990) (proposed excess profits tax after the holder of an Orphan Drug designation recaptures two times its developmental costs and generates up to 25% annual profit). The Orphan Drug Amendments of 1990, adopted by Congress and pocket vetoed by President Bush, provided loss of exclusivity once the patient population exceeds 200,000 and for shared exclusivity in the case of simultaneous discovery where the drug was predicted to be profitable from the start. H.R. 4638, 101st Cong., 2d Sess. (1990).

43. Mezrich, *supra* note 26, at 83-84; Tregarthen, *supra* note 21, at A13.

44. Mezrich, *supra* note 26, at 85.

45. Tregarthen, *supra* note 21, at A13.

Drug designation for Taxol, Bristol-Meyers Squibb, through a cooperative research and development agreement giving Bristol exclusive rights to all pacific yew trees on federal lands.⁴⁶ The agreement is no different than the grant of royal franchises and monopolies condemned four centuries ago by the Statute of Monopolies.⁴⁷

Throughout its relatively short life, the Orphan Drug Act has proved to be a source of controversy, particularly the grant of seven years of marketing exclusivity conferring an exclusive monopoly over the sale of designated Orphan Drugs. To date the debates have concerned whether Congress should or should not have granted such a monopoly or whether it should modify the monopoly granted to prevent the abuses which have arisen. No

46. Love, *supra* note 11, at 1. On average, the bark of four Pacific Yew trees is required to produce a sufficient amount of Taxol to treat one patient. Marilyn Chase, *Scientists Say Progress Is Made in Taxol Search*, WALL ST. J., March 18, 1992, at B1. Extensive research is taking place with the objective of artificially synthesizing the Taxol molecule's "central core." *Id.*

47. The Statute of Monopolies provided in part:

"[A]ll monopolies, and all commissions, grants, licenses, charters, and letters-patent, heretofore made or granted, or hereafter to be made or granted, to any person or persons, bodies politic or corporate whatsoever, of or for the sole buying, selling, making, working or using of anything, within this realm or the dominion of Wales, or of any other monopolies," and all licenses to do anything contrary to law "are altogether contrary to the laws of this realm, and so are and shall be utterly void"

1 ERNEST P. LIPSCOMB III, WALKER ON PATENTS § 1.15 (3d ed. 1985) (quoting English Statute of Monopolies, 21 Jac. 1 ch. 3 (1623)).

The practice of sanctioning patents on discoveries made with the assistance of federal funds under 35 U.S.C. §§ 200-11 (1988) and transferring discoveries made in government labs under the Federal Technology Transfer Act, 15 U.S.C. §§ 3701-3711a (1988), raises the possible constitutional issue of circumventing the underlying philosophy of the Patent Clause by government action deterring the progress of science and the useful arts: In effect, a government subsidy is being used in addition to the patent incentive intended to induce private inventors to disclose ideas. Where the government obtains the patent right and then grants an exclusive license to the government-held patent, there is a circumvention of the purpose of the Patent Clause by government granting monopoly patent rights without any further disclosure of a new idea by the private beneficiary of the exclusive licence. Government funded research, either in government labs or private ones, should result in public access to the government produced new "Discoveries."

Otherwise, consumers end up paying twice for the invention: First, by funding the research, whether it be public or private; and, second, by the payment of monopoly prices for products using the patented idea or subject matter developed with federal funds. These issues are in need of serious study by Congress and reform of the practice of exclusive licensing of government held patents and more careful review of private ownership interests in patents derived from federally funded research. For a discussion of some of these issues, see Love, *supra* note 11, at 11-18.

one has raised the deeper and more serious question of whether Congress has the *power* to grant such a monopoly in the first instance and whether it may do so under the Commerce Clause rather than the Patent Clause of the Constitution.

It is the position of this Article that the Act's seven year exclusive marketing right confers a patent right without conforming to the limitations of the Patent Clause of the Constitution, and, in adopting the Act, Congress unconstitutionally exercised its power under the Commerce Clause in passing a statute creating a patent right it could only pass pursuant to and in conformity with the Patent Clause of the Constitution.⁴⁸ This conclusion means that the congressional grant of power to the FDA to confer rights of marketing exclusivity to designated suppliers of Orphan Drugs is unconstitutional, and those grants of exclusivity which the FDA has made are void and of no legal force and effect. Competing applicants for marketing existing Orphan Drugs are entitled to have their applications considered and implemented by the FDA and those paying monopoly prices for Orphan Drugs are being overcharged as the result of an unconstitutional statute precluding competition from determining the prices they pay for

48. There is another serious and substantial problem with the FDA's administration of the Act, beyond the scope of this Article, which deserves mention. The FDA refuses to hold hearings where there are two or more competing applicants for the use of the same drug for the same orphan disease. In its proposed Orphan Drug Regulations, 56 Fed. Reg. 3338, 3344 (1991) (to be codified at 21 C.F.R. § 316 (proposed Jan. 29, 1991)), the FDA asserts that "[n]either the Constitution, nor the Administrative Procedure Act, nor the Orphan Drug Act requires a hearing on any issue of this kind." This statement obviously conflicts with the *Ashbacker* doctrine set forth in *Ashbacker Radio Corp. v. F.C.C.*, 326 U.S. 327 (1945), requiring a hearing where there are two mutually exclusive applications for a governmental license. *Id.* at 329-30. That the statute does not provide for a hearing is not dispositive. *Wong Yang Sung v. McGrath*, 339 U.S. 33, 49-50 (1950). In addition, § 9(b) of the Administrative Procedure Act ("APA") expressly provides:

When application is made for a license required by law, the agency, with due regard for the rights and privileges of all interested parties or adversely affected persons and within a reasonable time, shall set and complete proceedings required to be conducted in accordance with sections 556 and 557 of this title or other proceedings required by law and shall make its decision.

5 U.S.C. § 558(c) (1988).

The refusal of the FDA to comply with the hearing requirements of the APA is also a politically unwise policy because it leaves the agency with secret and unreviewable decision-making power in handing out exclusive rights of great economic value. It is inevitable that charges ranging from favoritism to corruption will arise in such circumstances, whether real or imagined, and the integrity of the Agency will be constantly at risk with so much at stake in receiving a grant of market exclusivity.

their medication.

II. CONSTITUTIONAL DIFFICULTIES WITH THE ORPHAN DRUG ACT

A. *Patent Clause Limitations on the Power Of Congress*

The Patent Clause of the United States Constitution provides that Congress shall have power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."⁴⁹ The power conferred has long been recognized as being only for the limited public purpose of promoting the progress of science and useful arts; reward to the inventor is secondary and subservient to this public purpose.⁵⁰ Consequently,

it is well settled that Congress cannot constitutionally enact legislation conferring exclusive patent rights upon discoverers

49. U.S. CONST., art. I, § 8, cl. 8.

50. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510-11 (1917):

Since *Pennock v. Dialogue* [27 U.S. (2 Pet.) 1 (1829)] was decided in 1829 this court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is "to promote the progress of science and useful arts" an object and purpose authoritatively expressed by Mr. Justice Story, in that decision, saying:

"While one great object [of our patent laws] was, by holding out a reasonable reward to inventors, and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius; the main object was 'to promote the progress of science and useful arts.'"

Thirty years later this court, returning to the subject in *Kendall v. Winsor* [62 U.S. (21 How.) 322 (1858)], again pointedly and significantly says:

"It is undeniably true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly."

Id. at 510-11 (citations omitted).

of subject matter that is not "new." Similarly, abstract thoughts and theories including mechanical and scientific principles and laws of nature, though constituting "discoveries" of the most fundamental sort, are not within the scope of congressional prerogative under the patent clause of the Constitution, because exclusive appropriation, even for a limited period, would rob the public of access to elemental building blocks of creative thought and thereby stifle "Progress of Science and useful Arts." Consonant with these principles, every patent statute enacted by Congress under the Constitution has carefully defined the inventions for which patents may be granted as products or processes (i.e., "arts") that are both new and useful. It is likewise settled, consistent with every patent statute so far enacted, that under the Constitution the patent right must be confined to a limited time, must be an exclusive right, and must be secured only to "inventors."⁵¹

The history of the patent clause, traceable to European and English experience with unfettered sovereign grants of exclusive privileges or state monopolies,⁵² suggests that it was intended to be both a carefully crafted and limited power and one carrying the implication that congressional power to create otherwise unregulated monopolies is confined to the limited public purpose stated in the Patent Clause and constrained by the conditions expressly placed upon congressional exercise of that power.

One set of problems with the Orphan Drug Act is that the creation of the seven year exclusive marketing right for drugs to treat orphan diseases has all the earmarks of the creation of a patent right.⁵³ But the statute does not conform to the express

51. Edward S. Irons and Mary H. Sears, *The Constitutional Standard of Invention—The Touchstone for Patent Reform*, 1973 UTAH L. REV. 653, 654 (citations omitted).

52. *Id.* at 658-62.

53. The length of the grant of exclusivity conferred by the Orphan Drug Act, seven years, coincides with the common law length of the monopoly granted over industrial processes. The common law grant was based on the institution of seven-year apprenticeships. See Dale A. Nance, *Forward, Owning Ideas*, 13 HARV. J.L. & PUB. POL'Y 757, 760 (1990). See generally BRUCE W. BUGBEE, *THE GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW* (1967). The length of "limited times" for which Congress may adopt laws conferring patent rights is not spelled out in the Constitution. Originally, the term was for 14 years, twice the term of the common law grant of a monopoly over industrial processes and apprenticeships. See generally Desrosiers, *supra* note 2 (discussing drug patent terms). The fact that the exclusive marketing right under the Orphan Drug Act

limitations upon the exercise of the patent power because: (1) the Orphan Drug Act was not adopted to promote "the Progress of Science and the Useful Arts" by securing the disclosure of "Discoveries," but is designed to give an economic incentive to drug manufacturers to invest in developing drugs for rare diseases whether they meet the standard of being contributions to the progress of science and the useful arts or not;⁵⁴ (2) drugs qualifying for Orphan Drug status need not meet the new "Discoveries" or innovation standard required by the Patent Clause of the Constitution in order to receive the seven year marketing monopoly authorized by the Act;⁵⁵ and (3) the right of exclusivity can be

is for seven years has no implication for the question of whether the Act grants a patent right or not because it is the grant of an otherwise unregulated right to have others excluded for "limited times."

54. There is a deeper set of philosophical issues with regard to the reasons for sanctioning a governmental power to grant a monopoly over ideas in a free society. Is the purpose of doing so the vesting of a property like right in those contributing the idea to the common fund of knowledge, or is it a utilitarian recognition of the need to provide an incentive to the creators of ideas so that inventors will reveal their ideas to the public in order to promote further innovation and the progress of science and the useful arts? Are the rights created "property" rights or the temporary creation of a private franchise to fulfill the goal of advancing the public interest of progress in science and the useful arts and only to the extent necessary to induce disclosure? For a thoughtful and full exploration of these issues, see Symposium on Law and Philosophy, 13 HARV. J. L. & PUB. POL'Y No. 3 (1990).

Whichever view one takes, it is unusual for a free society to carve out certain ideas and the expressions of them for grants of individual monopolies. Nance, *supra* note 53, at 761-67. Because of this and the underlying principle that the federal government is one of limited and delegated powers, exercise of the power granted by the Patent Clause should be held to a high standard of conformity to the public purpose of the grant of the power and the express constitutional limitations upon its exercise. Consequently, legislation implementing the powers granted by the Patent Clause should be exercised "only for a limited purpose—to promote the Progress of Science and useful Arts." Irons & Sears, *supra* note 51, at 653.

55. Consistent with the Constitutional requirement of novelty, the Patent Code imposes three interrelated conditions for patentability: novelty, utility, and non-obviousness. Title 35 U.S.C. § 101 requires that an invention or discovery be "new and useful." 35 U.S.C. § 101 (1988). Title 35 U.S.C. § 102 precludes the issuance of a patent where the invention is anticipated in the prior art. *Id.* § 102. Title 35 U.S.C. § 103 precludes issuance of a patent where "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *Id.* § 103. The Supreme Court has long acknowledged that under the Constitution, as well as the Patent Code, "that there be some 'invention' to be entitled to patent protection." *Sakraidia v. Ag Pro, Inc.*, 425 U.S. 273, 279 (1976); *see also* *Shaw v. Cooper*, 32 U.S. (7 Pet.) 292, 320 (1833). The FDA does not and is not authorized or competent to make these kinds of evaluations under the Orphan Drug Act.

The meaning of the concept "invention" has had a long and controversial history.

granted to a non-inventor in violation of the express limitation of the patent clause of "securing" patent rights only to "Inventors."⁵⁶ A second set of issues arises because Congress adopted the Act pursuant to its power to regulate commerce, and if the Act results in the creation of a patent right, the question is raised as to whether Congress can adopt laws pursuant to one of its delegated powers that it is specifically authorized to adopt by a carefully limited grant of power found in another.

*B. The Nature of Patent Rights and Limitations
on Congressional Exercise of the Patent Power*

"It must never be forgotten that the federal government is one of enumerated powers and that it does not possess a general

See E. Wyndham Hulme, *The History of the Patent System Under the Prerogative and at Common Law*, 12 L.Q. REV. 141 (1896); Frank D. Prager, *Standards of Patentable Invention From 1474 to 1952*, 20 U. CHI. L. REV. 69 (1952). Considerable controversy exists because of Supreme Court language in cases like *Sakraida* seemingly establishing a higher standard of invention than that required by 35 U.S.C. § 103, a decision the United States Court of Appeals for the Federal Circuit has been undermining. Whatever level of "invention" one wishes to argue for, it is clear that the Constitution does require that a patent only be issued for "Discoveries" promoting the "progress of science and useful arts." The Orphan Drug Act contains no requirement of invention or that the designated drug be a new "Discovery", even if one disregards the manner in which the invention was made, in order to gain seven years of market exclusivity.

56. The limitation upon the grant of a patent to a non-inventor is explicit in the Constitution and has been a strictly enforced and consistent requirement of the patent laws. The Supreme Court has held that the granting of a patent to a non-inventor results in the invalidity of the patent. In *Kennedy v. Hazelton*, 128 U.S. 667, 672 (1888), the Court held:

A patent which is not supported by the oath of the inventor, but applied for by one who is not the inventor, is unauthorized by law, and void, and, whether taken out in the name of the applicant or any assignee of his, confers no rights against the public. . . . [A] court of equity will not order him to assign it to the plaintiff . . . because its only possible value or use to the plaintiff would be to enable him to impose upon the public by asserting rights under a void patent.

Id. at 672 (citations omitted). See generally 1 LIPSCOMB, *supra* note 47, §§ 3.1, 3.2.

Consistent with the requirement of the Constitution that a patent may only be granted to "Inventors", the Patent Code precludes issuance of a patent to anyone other than the inventor of the subject matter sought to be patented. See 35 U.S.C. § 102(f) (1988). Courts are liberal in permitting correction of mistakes in designating the inventor.

police power."⁵⁷ Each of the branches of the Federal Government can only act pursuant to and within the limits of a specific grant of power found in the Constitution. The principal delegation of powers to Congress, powers limited by the introductory language of Article 1, section 1 conferring only the "legislative powers herein granted,"⁵⁸ is found in Article 1, section 8 of the Constitution. All of the powers granted are inherently limited by the terms of the grant and some of them have express conditions attached to the exercise of the power granted, as, for example, the requirement that rules on naturalization and bankruptcy be "uniform." Article I, section 9 goes further to specify categories of laws which may not be enacted pursuant to the limited powers granted Congress. That the powers granted are limited ones is reaffirmed by the Tenth Amendment, which provides: "powers not delegated to the United States by the Constitution . . . are reserved to the States respectively, or to the people".

The United States Supreme Court has long recognized that the Patent Clause of the Constitution expressly limits the power of Congress to enact legislation granting patent rights. In *Graham v. John Deere Co.*,⁵⁹ the Court held:

The [Patent] clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the 'useful arts.' . . . The Congress in the exercise of the patent power

57. JOHN E. NOWAK ET AL., CONSTITUTIONAL LAW 128 (3d ed. 1986).

58. LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 5-1, at 297 (2d ed. 1988). Professor Tribe notes that the Supreme Court has "largely abandoned any efforts to articulate and enforce internal limits on congressional power—limits inherent in the grants of powers themselves." *Id.* Instead he suggests that the Court has been concerned primarily with developing "external" or structural limits on the powers of Congress through devices like the separation of powers and federalism. *Id.*

These observations concern attempts to limit the scope of grants of power like the commerce power by the terms of the grant itself. The circumstances presented by the Orphan Drug Act concern limitations upon one grant of power imposed by another. The two grants of power involved in the case of the Orphan Drug Act both appear within the same section of the Constitution. *See* U.S. CONST., art. I, § 8. Consequently, the issue presented here is not only the limited nature of the grants of delegated power to Congress, but an interpretation of how the grant of the general commerce power relates to the grant of the limited patent power and whether the former can be used to override or circumvent the limitations upon the latter.

59. 383 U.S. 1 (1966).

may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. . . . Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.' This is the standard expressed in the Constitution and it may not be ignored.⁶⁰

In the earlier case of *Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*,⁶¹ Justice Douglas in concurrence emphasized the same theme when he stated:

It is worth emphasis that every patent case involving validity presents a question which requires reference to a standard written into the Constitution. Article 1, section 8 contains a grant to the Congress of the power to permit patents to be issued. But, unlike most of the specific powers which Congress is given, that grant is qualified. The Congress does not have free rein, for example, to decide that patents should be easily or freely given. The Congress acts under the restraint imposed by the statement of purpose in Art. I, § 8. The purpose is "To promote the Progress of Science and useful Arts" The means for achievement of that end is the grant for a limited time to inventors of the exclusive right to their inventions.

Every patent is the grant of a privilege of exacting tolls from the public. The Framers plainly did not want those monopolies freely granted. The invention, to justify a patent, had to serve the ends of science—to push back the frontiers of chemistry, physics, and the like; to make a distinctive contribution to scientific knowledge. That is why through the years the opinions of the Court commonly have taken "inventive genius"⁶² as the test. It is not enough that the article is

60. *Id.* at 5-6.

61. 340 U.S. 147 (1950).

62. [by the Author] See also *Cuno Eng. Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941), where Justice Douglas required a showing of "creative genius" for patentability. The concepts of "inventive" and "creative genius" have created considerable controversy and long standing debates concerning the standard or level of "invention"

new and useful. The Constitution never sanctioned the patenting of gadgets. Patents serve a higher end—the advancement of science. An invention need not be as startling as an atomic bomb to be patentable. But it has to be of such quality and distinction that masters of the scientific field in which it falls will recognize it as an advance.⁶³

While some have criticized these holdings,⁶⁴ they are decisions in accord with long-standing Supreme Court decisions concerning the constitutional limitations of the Patent Clause upon the power of Congress to create patent rights.⁶⁵

In 1989 the Court reaffirmed its holding that the patent clause is both a grant and a limitation of power to the federal government. In *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,⁶⁶ a preemption case, the Court affirmed a Florida Supreme Court judgment striking down a Florida statute which prohibited the use of a direct molding process to duplicate unpatented boat hulls.⁶⁷ In the course of the opinion finding the Florida statute conflicted with the balance struck by the Constitution in the Patent Clause and by Congress in the federal patent laws between the encouragement of invention and free competition in unpatented ideas, Justice O'Connor speaking for a unanimous Court stated:

The Patent Clause [of the Constitution] itself reflects a

which should be required for patentability on both a constitutional and statutory basis. See Prager, *supra* note 55, at 69-70. Some view the amendment to 35 U.S.C. § 103, providing that "[p]atentability shall not be negated by the manner in which the invention was made," Pub. L. No. 593, 66 Stat. 798 (codified at 35 U.S.C. § 103 (1988)), as modifying Justice Douglas's test of "creative genius" and tests like that put forth by Thurman Arnold in *Potts v. Coe*, 145 F.2d 27, 28 (D.C. Cir. 1944) imposing a higher standard of invention upon corporate research labs. Whether this is the case or not as a matter of statutory construction, the issue here is the Constitutional standard mandated by the requirement that patents may only be granted for "Discoveries" promoting the "progress of Science and Useful Arts."

63. 340 U.S. at 154.

64. See, e.g., Albert B. Kimball, Jr., *An Analysis of Recent Supreme Court Assertions Regarding A Constitutional Standard of Invention*, 1 AM. PAT. L. ASS'N Q.J. 204 (1973).

65. See, e.g., *Thompson v. Boisselier*, 114 U.S. 1, 11 (1885); *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59, 73 (1885). See generally *Irons & Sears*, *supra* note 51, *passim* (discussing requirements for invention in United States).

66. 489 U.S. 141 (1989).

67. This result was predicted and explored by John B. Sganga, *Direct Molding Statutes: Potent Weapons, but are they Constitutional*, 71 J. PAT. OFF. & TRADEMARK SOC'Y 71 (1989).

balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the "Progress of Science and the useful Arts." As we have noted in the past, the clause contains both a grant of power and certain limitations upon the exercise of that power. Congress may not create patent monopolies of unlimited duration, nor may it "authorize the issuance of patents whose effects are to remove existent knowledge from the public domain or to restrict free access to materials already available." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6, 86 S. Ct. 684, 688, 15 L. Ed. 2d 545 (1966).

From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.⁶⁸

Justice O'Connor went on to note that the patent laws have always excluded from consideration for patent protection knowledge which is already available to the public. Citing Justice Story's opinion in *Pennock v. Dialogue*,⁶⁹ Justice O'Connor wrote:

the federal patent scheme creates a limited opportunity to obtain a property right in an idea. Once an inventor has decided to lift the veil of secrecy from his work, he must choose between the protection of a federal patent or the dedication of his idea to the public at large.⁷⁰

In addition to the requirements of novelty and utility, Justice O'Connor noted that the federal patent law has "long required that an innovation not be anticipated by prior art in the field" and that "[t]aken together, the novelty and nonobviousness requirements express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of that which is either already available to the public,

68. 489 U.S. at 146 (citations omitted).

69. 27 U.S. (2 Pet.) 1 (1829), a case involving an attempt to patent a new technique for the manufacture of rubber hose seven years after it had first been reduced to practice and sold to the public.

70. 489 U.S. at 149.

or that which may be readily discerned from publicly available material."⁷¹ The opinion further states:

The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and non-obvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. . . .

The attractiveness of such a bargain, and its effectiveness in inducing creative effort and disclosure of the results of that effort, depend almost entirely on a backdrop of free competition in the exploitation of unpatented designs and innovations. The novelty and nonobviousness requirements of patentability embody a congressional understanding, implicit in the Patent Clause itself, that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception.⁷²

The Court's decision in the *Bonito Boats* case reflects the well established understanding that the Patent Clause of the Constitution prevents Congress from creating: (1) patent rights of unlimited duration; (2) patent rights where there is no conferring of the public benefit of promoting the progress of science and useful arts; (3) patent rights where the effect of a grant of exclusivity is to restrict free access to materials in the public domain or which displace free competition in the exploitation of innovation not rising to the constitutional level of "Discoveries"; or, (4) patent rights which are conferred upon non-inventors.⁷³ On its face and

71. *Id.*

72. *Id.* at 150-51.

73. *Id.* at 145-54. The further argument made by some that Congress may not grant inventors less than absolute exclusivity in their ideas is not listed as a constitutional constraint upon the power of Congress to grant less than an absolute right of exclusivity in view of the primacy of the public purpose of promoting the Progress of Science and the Useful Arts. This argument is put forward with respect to laws permitting some level of use of patented ideas by non-patent holders in the drug area for research. See Patti, *supra* note 26, at 567. Such an argument elevates reward to the inventor above the public purpose expressly stated in the Constitution and assumes that Congress is not free to enact patent laws or exercise less than the full power granted by the Patent Clause in a manner consistent with the public purpose of promoting the progress of science and the useful arts. The constitutional restrictions of "Discoveries," "limited times," and "Inventors" are all directly related to insuring the primary purpose of delegating power to Congress to adopt a patent system is the public one of "promoting the progress of Science and Useful Arts."

as applied, the Orphan Drug Act violates the above list of constraints upon Congressional power to create patent rights, save the limitation upon creating patent rights of unlimited duration, if it is found that the Act creates a "patent right" falling within this list of constraints upon Congressional power to enact patent laws.

The dictionary definition of a "patent" has been generally stated to be a "grant of some privilege, property or authority made by government or the sovereign of a country to one or more individuals" and more particularly as a "grant of the right to exclude others."⁷⁴ The Latin derivation of the words "letters patent," *litterae patentes*, means "open letters" or an open letter or document from a sovereign for specific purposes.⁷⁵ A standard definition of the patent right is that it is the conferring by government of an exclusive and unregulated right to make, to use, or to vend a new and useful invention.⁷⁶ The meaning of the concept "patent right" is deeply dependent upon the history of patents. That history is intertwined with the practice of the English Crown of granting royal monopolies or exclusive privileges or franchises over the right to engage in trade, as well as over new discoveries, to favored members of the Court. The practice generated great political opposition in England and resulted in the

74. BLACK'S LAW DICTIONARY 1125 (6th ed. 1990).

75. 1 LIPSCOMB, *supra* note 47, § 1.1.

76. The grant of either an exclusive right to make, or to use, or to vend can constitute a patent right. Title 35 U.S.C. § 154 states: "Every patent shall contain . . . a grant to the patentee, his heirs or assigns . . . of the right to exclude others from making, using, or selling the invention throughout the United States . . ." 35 U.S.C. § 154 (1988).

The issue of whether an idea granted a governmental monopoly is a patent right can arise under § 102 of the Patent Code, the novelty requirement. *Id.* § 102. Section 102 bars the grant of a patent where an invention is patented elsewhere before the applicant's invention or one year before the filing of an application. *Id.* Thus, issuance in a foreign country of a patent-like right prior to the U.S. application, will bar the grant of a U.S. patent where the foreign grant is found to be the equivalent of a patent. For example, in *Atlas Glass Co. v. Simonds Mfg.*, 102 F. 643 (3rd Cir. 1900), the court held that a Danish "eneret" was a patent within the meaning of § 102 even though it conferred only the exclusive right to make the patented device in Denmark. *Id.* at 646-47. The court held the essence of a patent right is the grant of an exclusive privilege from a sovereign where the privilege amounts to a substantial monopoly over making the subject matter. *Id.* at 646. The government grant of an exclusive and unregulated right to vend, standing alone, is consistently recognized as the grant of a patent right by cases dealing with the validity of state laws creating such a right and challenged on preemption grounds.

adoption of the Statute of Monopolies.⁷⁷ That law declared that the granting of "[a]ll monopolies and all commissions, grants, licenses, charters and letters patent" was "contrary to the laws of this realm and so are and shall be utterly void." The law made an exception for "letters patents and grants of privilege for the term of fourteen years or under . . . of the sole working or making of any manner of new manufacture within this realm, to the true and first inventor or inventors of such manufactures"⁷⁸

Letters patent were a species of royal grants of exclusive rights within the genus of sovereign-created exclusive monopoly rights to exclude others from a business or a trade, a form of sovereign franchise of monopoly rights granted for a limited time and only to inventors of new ideas. All other exclusive letters patents or sovereign grants of exclusive rights were deemed to be null and void—the implicit result found in the Constitution by spelling out a power to regulate commerce and the express limitation upon the granting of monopolies spelled out in the Patent Clause.

Continuation of the practice of granting royal monopolies and their imposition on the American colonies directly contributed to the American Revolution and the institution of a democratic governments of limited powers. Colonial governments adopted general prohibitions upon the creation of monopolies, with narrow and limited exceptions for new inventions that benefitted the community and were granted only for a short time.⁷⁹ An underlying philosophy in favor of every person having the freedom to use

77. 21 Jac. 1, c. 3 (1623), reprinted in LOUIS B. SCHWARTZ, JOHN J. FLYNN & HARRY FIRST, *FREE ENTERPRISE AND ECONOMIC ORGANIZATION: ANTITRUST 1-2* (6th ed. 1983). See generally BUGBEE, *supra* note 53, *passim*.

78. 21 Jac. 1, c. 3, reprinted in SCHWARTZ, FLYNN & FIRST, *supra* note 77, at 1-2. Coke's *Second Institute, Commentary on Magna Carta*, published in 1642 listed among the great "liberties" guaranteed by Magna Carta a prohibition upon the creation of monopolies. *Id.* Coke stated:

[I]f a graunt be made to any man, to have the sole making of cards, or the sole dealing with any other trade, that graunt is against the liberty and freedom of the subject, that before did, or lawfully might have used that trade, and consequently this great charter

Generally all monopolies are against this great charter, because they are against the liberty and freedom of the subject, and against the law of the land.

Coke's *Second Institute, Commentary on Magna Carta*, reprinted in ROSCOE POUND, *THE DEVELOPMENT OF CONSTITUTIONAL GUARANTEES OF LIBERTY* 150 (1957).

79. Irons & Sears, *supra* note 51, at 664-67.

ideas—with an exception made only to the extent that the public would benefit by giving an exclusive franchise over a new discovery to the inventor for a limited time in order to stimulate disclosure of the idea so that progress in science could take place suffused the times—resulted in the drafting of the limited power found in the Patent Clause of the Constitution.⁸⁰ No express power was granted Congress to create otherwise unlimited and unregulated monopolies generally and it can clearly be maintained that the Patent Clause was not only a narrowly crafted exception to the underlying philosophy in favor of every person having the freedom to use ideas otherwise in the public domain, but that it is also an expression of a prohibition: that the federal government is precluded from granting any otherwise unregulated and exclusive monopoly to an individual or firm other than those conforming to the limitations of the Patent Clause.⁸¹

Modern American patent law is directly traceable to the

80. *Id.* at 669-71. There is a rich scholarship seeking to explain the economic justifications for and against a patent system. See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977); Mark R. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 311-49 (1992). Such scholarship is relevant to the decision of Congress to adopt patent laws and the decision of what the scope of the laws adopted should or should not be. It is only marginally relevant to the issues addressed here concerning the constitutional minimum which must be observed by Congress in adopting and defining the scope of laws creating patent rights.

81. Although unnecessary to the analysis of and beyond the scope of this Article, it is submitted that from an historical point of view, and in light of the reasons for the Revolutionary War and the circumstances surrounding the drafting of the United States Constitution, the Commerce Clause and the Patent Clause should be read together as establishing an implicit policy of precluding the federal government from granting private parties unregulated and exclusive monopolies over economic activity other than that authorized by the Patent Clause. The court practice of reading regulatory statutes strictly and in light of an in-going presumption in favor of competition regulating private economic activity not otherwise specifically regulated is a manifestation of this basic policy. See *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 335-72 (1963); Louis B. Schwartz, *Legal Restriction of Competition In the Regulated Industries: An Abdication of Judicial Responsibility*, 67 HARV. L. REV. 436 *passim* (1954). The recent tendency of Congress to adopt statutes like the Cable Communications Policy Act of 1984, Pub. L. No. 98-544, 98 Stat. 2279 (codified as amended at 47 U.S.C.A. §§ 521-559 (West 1991)), precluding governmental rate regulation of local monopolies in the cable industry, are of questionable constitutional validity, save for the often unrealistic possibility that new entry may constrain otherwise unlimited monopoly pricing discretion of the monopolists. Congress, if not the courts, should develop a basic policy of refusing to create unregulated monopolies because of their obvious potential for imposing economic harm upon the public, if not because of the questionable constitutional power of Congress to even consider the possibility. On the other hand, this may be asking too much of a Congress dominated by political action committees.

common law policy of banning government granted monopolies in favor of free and open competition⁸² and the Statute of Monopolies, with a limited and narrow exception made for patents granted for limited times to inventors of new and useful ideas fostering science and the useful arts in exchange for disclosing and dedicating the idea to the public domain. Viewed in this way, it is clear that the patent system is an important and integral component of the competitive process because the incentives of a form of quasi-property protection⁸³ granted to inventors for a limited time are recognized as a part of the public interest in securing disclosure of new and useful ideas which will lead to further creativity and competition in improving on the ideas divulged by the patent.⁸⁴

82. Twenty one years prior to the adoption of the Statute of Monopolies, the common law was relied upon to strike down the Royal grant of a monopoly over the importation and manufacture of playing cards in *The Case of Monopolies, Darcy v. Allein*, 11 Coke 84b, 77 Eng. Rep. 1260, 1263-64 (K.B. 1602). The King's Bench found that "the Queen was deceived in her grant, . . . as by the preamble appears, intended it to be for the weal public; and it will be employed for the private gain of the patentee, and for the prejudice of the weal public" Consequently, the Court held that the Act was "utterly void" under Magna Charta and the common law. *Id.* at 1265. See generally William C. Letwin, *The English Common Law Concerning Monopolies*, 21 U. CHI. L. REV. 355, 356-79 (1954); D. Seaborne Davies, *Further Light on the Case of Monopolies*, 48 L.Q. REV. 394 *passim* (1932) (discussing history of monopolies under English common law).

83. The doctrine of patent misuse, independent of antitrust constraints upon the use made of patent rights, restricts the patent holder from requiring the purchase of unpatented items in conjunction patented technology, imposing restraints upon a patent licensee from selling competing goods, or conditioning the grant of a patent license on an unrelated license. As such, the doctrine is a recognition of the limited nature of the rights granted by a patent: "that the patentee receives nothing from the law which he did not have before, and that the only effect of his patent is to restrain others from manufacturing, using or selling that which he has invented." *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917). The doctrine is an illustration of the less than full spectrum of property rights vested in a patentee, causing courts and commentators to describe patent rights as a form of "quasi-property" rights rather than "property" rights. On the general nature of "property rights, see John J. Flynn, *The Chicken and the Egg* in FUNDAMENTALS OF THE ECONOMIC ROLE OF GOVERNMENT 69 (Warren J. Samuels ed., 1989).

84. See *Potts v. Coe*, 145 F.2d 27 (D.C. Cir. 1944) (Thurman Arnold's controversial decision requiring a higher level of invention for discoveries from corporate research labs in order to secure the true promotion of science and the useful arts. It is a decision which may have been modified as a matter of statutory interpretation by language added to 35 U.S.C. § 103); see also *supra* note 62 (discussing *Potts* decision).

For a tracing of the historical roots of the Patent Clause and the constitutional standard for patent laws, see BUGBEE, *supra* note 53, *passim*; 1 LIPSCOMB, *supra* note 47, ch.1; Irons & Sears, *supra* note 51, at 653-58, 663-78. It should be noted that there is considerable criticism of the need and justification for exercising the power to grant sovereign protection of ideas in the form of patents, copyrights and other forms of intellectual property. See generally Symposium, *supra* note 54, at 757.

Consequently, the key elements of a patent right are that it is the governmental conferring of an otherwise unregulated and exclusive monopoly right "to exclude others from the making, using or vending of the thing patented without the permission of the patentee."⁸⁵ And, because of the express language of the Patent Clause, it is a right that can be conferred only for the purpose of promoting the progress of science and the useful arts and only for a limited time to inventors of new and useful discoveries.⁸⁶ These limitations are imposed to fulfill the underlying purpose of granting the federal government the exclusive power to create patent rights; namely to secure the disclosure of new inventions so that society may benefit from that disclosure by knowing and understanding the idea patented. The basic objective of disclosure is the public one of stimulating further invention and creativity by securing disclosure and not the private one of simulating investment like that done through subsidies, tax credits, and the conferring of exclusive rights without the *quid pro quo* of the specific public benefit of promoting progress in science and the useful arts.

85. *Bloomer v. McQuewan*, 55 U.S. 538, 549 (1853); *see also* *United Shoe Mach. Corp. v. United States*, 258 U.S. 451, 463 (1922) ("[T]he franchise secured by a patent consists only in the right to exclude others from making, using, or vending the thing patented without the permission of the patentee.").

86. The requirement that the patented subject matter be both new and "useful" emphasizes the public purpose of the patent system. Granting patent protection to a new idea where there is no known use for the idea is precluded by the utility requirement. In *Brenner v. Manson*, 383 U.S. 519 (1966), Justice Fortas, writing for the Court, explained why "utility" has been a consistent requirement for patentability:

Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast and unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Id. at 534-35 (citations omitted).

Some may argue that recognition of the limitations upon Congress's power to confer patent rights may place in jeopardy a wide range of potentially similar rights of exclusivity. For example, Congress has conferred exclusive rights upon public utilities to provide interstate gas⁸⁷ and electricity transmission service⁸⁸ and has conferred upon television and radio broadcasters exclusive frequencies to transmit their signals.⁸⁹ In neither gas nor electricity regulation has Congress conferred unregulated rights of exclusivity. The public need for avoiding the unnecessary duplication of utility plant to serve the public requiring the grant of a certificate of public convenience and necessity before one may undertake offering the service has been accompanied by both rate regulation and competition.⁹⁰ Moreover the public objective of avoiding the expense of unnecessary duplication of facilities clearly distinguishes any grant of exclusivity from the unregulated one granted by the patent laws and clearly justifies the issuance of the certificate of public convenience and necessity under the Commerce Clause, while affirmative rate regulation avoids the abuse the limitations of the Patent Clause place upon the explicit power of Congress to authorize the issuance of exclusive quasi-property rights in the form of patents for a limited time.⁹¹

Similarly, in the case of radio and television broadcasting the need to rationalize use of the limited radio spectrum to prevent interference and the licensing of competing broadcasters both justify the issuance of exclusive certificates to a portion of the spectrum for a limited time in order to make any use of the publicly owned airwaves at all.⁹² Licensing competing broadcasters avoids the abuses that the limitations of the Patent Clause were designed to prevent in the case of Congressional grants of exclusivity in writings and discoveries.⁹³ The rights granted are not patent

87. Natural Gas Act of 1938, 17 U.S.C.A. § 717(a)-(f) (West 1976 & Supp. 1992).

88. Federal Power Act of 1936, 16 U.S.C. § 824(a)-(f) (1988 & Supp. II 1990).

89. The Communications Act of 1934, 47 U.S.C.A. §§ 151-58, 301-33 (West 1991).

90. See SCHWARTZ, FLYNN & FIRST, *supra* note 77, at 31-32.

91. For the rationales for rate regulation, see *id.* at 311-16.

92. See *F.C.C. v. Sanders Bros. Radio Station*, 309 U.S. 470, 474 (1940). "Unless Congress had exercised its power over interstate commerce to bring about allocation of available frequencies and to regulate the employment of transmission equipment the result would have been an impairment of the effective use of these facilities by anyone." *Id.*

93. See SCHWARTZ, FLYNN & FIRST, *supra* note 77, at 34-35.

rights—a government conferred and unregulated exclusive right to have others prevented from making, using or selling an idea or subject matter—but limited permission to make use of a public asset conferred by government for the benefit of the public in order to have any practical use of the radio spectrum at all and one controlled by competition from other licensees serving the same audience.

The nature of a "patent" right and the thin line between the creation of a patent right conferring an exclusive quasi-property right and other forms of regulated exclusivity not subject to the constitutional limits of the Patent Clause is perhaps best illustrated by cases dealing with the thorny issue of categorizing state law recognition of some realm of exclusivity over things of value and the patent laws. The Supreme Court has long held that the Patent Clause standing alone, like the dormant Commerce Clause and the patent laws, preempts state laws which create "patent-like" rights.⁹⁴ The Court has held:

State law protection for techniques and designs whose disclosure has already been induced by market rewards may conflict with the very purpose of the patent laws by decreasing the range of ideas available as the building blocks of further innovation.

. . . . [O]ur past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws. . . . Where the public has paid the congressionally mandated price for disclosure, the States may not render the exchange fruitless by offering patent-like protection to the subject matter of the expired patent.⁹⁵

The key issue in such cases is when does a state law create a "patent-like" right as opposed to some other type of right like a tort or contract right? Identification of the factors relied upon in these cases is an additional guide in determining whether the Orphan Drug Act creates patent-like rights subject to the limita-

94. See *Coats v. Merrick Thread Co.*, 149 U.S. 562, 572 (1893); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 117 (1938); *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 203-04 (1898); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151-57 (1991).

95. *Bonito Boats, Inc.*, 489 U.S. at 151-52.

tions upon Congress's power to do so under the Patent Clause.⁹⁶

In *Sears Roebuck & Co. v. Stiffel Co.*,⁹⁷ and *Compco Corp. v. Day-Brite Lighting, Inc.*⁹⁸ the Court was confronted with cases requiring the Court to determine whether state laws of unfair competition created a form of property rights the equivalent of patent rights within the exclusive power of Congress to create or not create under the Patent Clause of the Constitution. In the *Sears* case the lower courts found that Stiffel's claim to a patent on the design of pole lamps was invalid due to anticipation in the prior art, but enjoined Sears from further sale of the lamps on a finding of consumer confusion under the Illinois law of unfair competition. The latter finding was based on the conclusion that the Illinois law of unfair competition prohibited product simulation even in the absence of evidence that the defendant took some additional steps beyond copying the design of the product to induce consumer confusion like the affirmative act of mislabeling the lamps. The Supreme Court reversed, holding that there was a right under the federal patent laws to copy the lamp design and sell identical lamps to the public. The Court held that the grant of a patent "is the grant of a statutory monopoly"⁹⁹ and that state law may not be permitted to create a similar monopoly.¹⁰⁰ State law may

in appropriate circumstances, require that goods, whether patented or unpatented, be labeled or that other precautionary steps be taken to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods.¹⁰¹

96. See generally Stephen L. Carter, *Owning What Doesn't Exist*, 13 HARV. J.L. & PUB. POLICY 99, 114-18 (1990) (criticizing *Bonito Boats* decision).

97. 376 U.S. 225 (1964).

98. 376 U.S. 234 (1964).

99. 376 U.S. at 229.

100. *Id.* at 231-32. To allow a state to use its law of unfair competition to prevent the copying of an article which represents too slight an advance to be patented would be to permit the state to block off from the public something which the federal law has said belongs to the public. See *id.*

101. *Id.* at 232 (footnote omitted).

The Court drew the distinction between state unfair trade practices law and a patent right at that point where state law crosses the line of protecting consumers from confusion to the creation of an exclusive property right whereby government excludes others and protects the claimant of the right from copying or vending the idea or subject matter by others without regard for consumer confusion and less restrictive means for preventing consumer confusion.¹⁰²

The Court reached a similar conclusion in *Compco*, a case involving the copying of the functional aspects of an unpatented fluorescent lighting system. The Court held that the granting of an injunction against copying of an unpatented article, freely available to the public, even where there is some evidence of confusion, unconstitutionally "interfere[d] with the federal policy found in Art. 1, cl. 8 of the Constitution and in the implementing federal statutes, of whatever the federal patent and copyright laws leave in the public domain."¹⁰³ The Court further held that whatever is left in the public domain by federal patent law, "can be copied in every detail by whoever pleases."¹⁰⁴

The Court was careful to draw a line permitting the states to have laws preventing active consumer deception by regulating conduct like mislabeling or unauthorized use of trademarks—laws which are designed not to create an exclusive property right in the holder of the trade dress or mark, but laws designed to protect consumers by preventing activity designed to mislead or defraud consumers.¹⁰⁵ Such laws are premised upon tort concepts and create duties to avoid fraud or misrepresentation; duties imposed by law to protect the public and not laws vesting a property-like right to exclude. The primary thrust of valid state laws regulating unfair competition is not the creation of property rights in the mark or product dress which would be rights belonging to the

102. *Id.* at 231-33. In recent years there has been an expansion of the use of state law tort principles and doctrines like misappropriation to expand claims of a right of protection for otherwise unprotected intellectual "property" interests. The trend is extensively examined and thoughtfully evaluated in Wendy J. Gordon, *On Owning Information: Intellectual Property and the Restitutory Impulse*, 78 VA. L. REV. 149, 150-70 (1992).

103. *Id.* at 237.

104. *Id.* at 238.

105. See also *Bonito Boats, Inc. v. Thunder Crafts Boats, Inc.*, 489 U.S. 141, 154-57 (1989).

property owner to exclude others even in the absence of consumer deception. The objective of such laws is to protect consumers from fraudulent and misleading conduct unfairly inducing consumers to purchase products they believe to be from one source when products originate with another.

Similarly, in the case of trade secrets, the Court has held that state laws aimed at protecting information not in the public domain are designed to protect a confidential relationship and protect contractual rights of privacy and are not the creation of a property-like right to exclude others from an idea.¹⁰⁶ The focus of the law in such cases is the recognition of both a contract and a tort right, relational rights designed to protect contractual relationships and enforce tort duties. Trade secret law is not designed to create a unilateral right to exclude others from an idea without more—the creation of a quasi-property right to exclude like the patent right. The underlying nature of trade secret rights as relational tort or contract rights and not property rights is clearly established by the uniform recognition that the holder of a trade secret right is not protected from independent discovery of the idea or from independent reverse engineering uncovering the secret.¹⁰⁷ The holder of a trade secret is protected only from tortious interference with rights of privacy or interference with contractual relationships requiring confidentiality and is not given an independent property-like right status to exclude all others from using the idea—the essence of the patent right.¹⁰⁸

106. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 491-94 (1974).

107. "A trade secret . . . does not offer protection against discovery by fair and honest means, such as independent invention, accidental disclosure, or by so-called reverse engineering" *Id.* at 476.

A trade secret may be a form of property interest for purposes of the Fifth Amendment's prohibition upon a takings of "private property for public use without just compensation." See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002-04 (1984). The concept of "property" for Fifth Amendment purposes embraces the takings of interests of value including such intangible interests as trade secrets, contract rights, *Lynch v. United States*, 292 U.S. 571, 579 (1934), and a lien interest. *Armstrong v. United States*, 364 U.S. 40, 45-46 (1960). The fact that a trade secret is "property" for Fifth Amendment purposes, of course, does not mean it is a property right for other purposes any more than a contract right becomes a property right for other purposes because it is considered "property" for Fifth Amendment purposes.

108. Justice Douglas correctly observed in his dissent in *Kewanee*:

A trade secret, unlike a patent, has no property dimension. That was the view of the Court of Appeals . . . and its decision is supported by what Mr. Justice Holmes said in *Du Pont Powder Co. v. Masland*, 244 U.S. 100, 102:

These cases therefore establish a relatively clear line defining patent-like rights as rights conferring upon an individual or firm what are in essence government created and enforced quasi-property rights to exclude others from making, using or vending an idea or subject matter, as distinguished from laws designed to protect contractual relations,¹⁰⁹ prevent tortious conduct or prevent consumer deception by deceitful mislabeling or misbranding of goods.¹¹⁰ As the Court noted in *Bonito Boats*:

"The word property as applied to trade-marks and trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence that he accepted. The property may be denied but the confidence cannot be. Therefore the starting point for the present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs, or one of them. These have given place to hostility, and the first thing to be made sure of is that the defendant shall not fraudulently abuse the trust reposed in him. It is the usual incident of confidential relations. If there is any disadvantage in the fact that he knew the plaintiff's secrets he must take the burden with the good."

A suit to redress theft of a trade secret is grounded in tort damages for breach of contract—a historic remedy. Damages for breach of a confidential relation are not pre-empted by this patent law, but an injunction against use is pre-empted because the patent law states the only monopoly over trade secrets that is enforceable by specific performance; and that monopoly exacts as a price full disclosure. A trade secret can be protected only by being kept secret. Damages for breach of a contract are one thing; an injunction barring disclosure does service for the protection accorded valid patents and is therefore pre-empted.

416 U.S. at 498-99 (citations omitted).

109. Misappropriation cases like *International News Serv. v. Associated Press*, 248 U.S. 215 (1918) come closest to inferring the existence of a property right and committing the courts to protecting the right even though it does not conform to the limitations of the Patent Clause. Where such cases are viewed as unfair competition cases constraining conduct which destroys the value created by the plaintiff through tortious means however, they too can be distinguished from laws creating independent rights to exclude others from an idea without regard for the means adopted by others to destroy the idea or value. So defined, they are narrow and traditional tort cases, not cases involving the vesting by law of a property-like right to exclude. See James A. Rahl, *The Right to Appropriate Trade Values*, 23 OHIO ST. L.J. 56 *passim* (1962).

110. The courts have also carefully limited the scope of state contract doctrine in the case of licensee estoppel or the extent to which a patent owner's licensing agreements are enforceable under state law where the underlying patent is invalid or the patent is being used to expand the scope of patent rights. The doctrine stems from the recognition that:

The law of unfair competition has its roots in the common-law tort of deceit: its general concern is with protecting *consumers* from confusion as to source. While that concern may result in the creation of "quasi-property rights" in communicative symbols, the focus is on the protection of consumers, not the protection of producers as an incentive to produce innovation.¹¹¹

A relatively clear line of demarcation between patent rights and state law recognition of a need to protect consumers from deception and the protection of contractual interests like trade secret rights can therefore be drawn on the basis of who is the intended and primary beneficiary of the policy being enforced. Such laws are designed to protect the public and contracting parties, not to confer quasi-property rights for the benefit of the holder of the right to have all others excluded from making or using or vending some idea or subject matter—a patent right. They are laws designed to protect employers and competitors from tortious conduct or violations of contractual responsibilities—common law matters within the jurisdiction of the states—and they are not the granting of independent property-like rights for the purpose of providing a profit incentive to encourage the disclosure of new inventions or to create independently

It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly; and it is a serious question whether public policy permits a man to barter away beforehand his right to defend unjust actions or classes of actions, though, in an individual case, he may doubtless assent that a judgment be rendered against him, even without notice.

Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892).

In *Lear, Inc. v. Adkins*, 395 U.S. 653, 668 (1969), the Court framed the conflict of policies as one where "the law of contracts forbids a purchaser to repudiate his promises simply because he later becomes dissatisfied with the bargain he has made"; while "federal law requires that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent." *Id.* The Court held that federal patent policy required that licensees be given the right to challenge the validity of the patent in question and, where the patent is found invalid, state law may not be used to compel the licensee to pay accrued royalties for the invalid patent. The use of state law to force payment of royalties on a pending patent was upheld in *Aronson v. Quick Point Pencil Co.*, because the Court treated the case as a contract case and that enforcement of the contract was similar to the enforcement of a trade secret license against a licensee even though the secret was subsequently disclosed. 440 U.S. 257, 264-64 (1979).

111. 489 U.S. at 157.

enforceable property interests in ideas or subject matter in order to promote the progress of science and useful arts.

In neither the case of federal regulation of natural monopolies or state unfair competition law and trade secret law is there a conferring of a market exclusion right upon an inventor or an investor in order to stimulate either investment or the disclosure of new inventions. And, in neither case is there the conferring of an exclusive monopoly right free of rate regulation or competition to prevent the abuses of an otherwise unregulated monopoly power to fix prices, control production, determine quality, regulate the rate of innovation, and exercise an unlimited power to allocate resources. In no case can federal or state law confer an exclusive quasi-property monopoly right with the primary objective of stimulating investment other than the only form of quasi-property monopoly right Congress is delegated the limited power to create by the Patent Power: the power to stimulate disclosure of truly inventive new ideas to promote the progress of science and the useful arts. All other grants of such unregulated rights invite the abuses of sovereign-conferred exclusive grants the Statute of Monopolies inveighed against more than four centuries ago. Consequently, where an unregulated and exclusive quasi-property right to exclude others from making, using or vending an idea or subject matter is granted by state or federal governments, a patent right has been created. It is a right which may only be created pursuant to and in conformity with the Patent Power of the Constitution.¹¹²

112. The Supreme Court has stated:

The grant of a patent is the grant of a statutory monopoly; indeed, the grant of patents in England was an explicit exception to the state of James I [The Statute of Monopolies] prohibiting monopolies. Patents are not given as favors, as was the case of monopolies given by the Tudor monarchs, but are meant to encourage invention by rewarding the inventor with the right, limited to a term of years fixed by the patent, to exclude others from the use of his invention. During that period of time no one may make, use, or sell the patented product without the patentee's authority. But in rewarding useful invention, the rights and welfare of the community must be fairly dealt with and effectually guarded. To that end the prerequisites to obtaining a patent are strictly observed, and when the patent has issued the limitations on its exercise are equally strictly enforced. To begin with, a genuine 'invention' or 'discovery' must demonstrated 'less in the constant demand for new appliances the heavy hand of tribute be laid on each slight technological advance in the art.' Once the patent issues, it is strictly construed, it cannot be used to secure any monopoly beyond that contained in the patent, the patentee's control over the product when it leaves his

*C. The Orphan Drug Act Unconstitutionally
Creates a Patent Right*

The effect of the Orphan Drug Act certification process and grant of seven years of marketing exclusivity before other applications will be considered by the FDA is the governmental conferring of a statutory monopoly—a patent right or patent-like right to be the exclusive vendor of the drug for a particular designation for a limited time. The right is an absolute one because anyone seeking to distribute a drug must first secure FDA approval to do so, and the FDA is precluded from granting a similar right to any other applicant unless the holder of the existing exclusive right cannot assure sufficient quantities of the drug to meet the designated need or unless the certificate holder consents.¹¹³ The exclusive right granted is even stronger than the exclusive right to vend under the patent laws because the certificate holder need not be an inventor and need take no action to enforce the right; the FDA is required by law to enforce the right for them by virtue of being precluded from permitting the sale of the drug by anyone else for the designated orphan disease. And, the scope of the right granted is broader than that permitted by the patent laws, because the subject matter need not amount to a new invention, can embrace a product of nature not otherwise patentable, and can be an active ingredient which has been "previously explored in academic or scientific literature" and is therefore obvious or previously disclosed.¹¹⁴

Like the exclusive rights granted by patent law, the right conferred by the Orphan Drug Act is a right not conditioned upon some event like the recovery of the costs associated with developing the drug or the costs of securing FDA approval of sale of the drug. It is a right whereby the certificate holder is free to charge

hand is sharply limited, and the patent monopoly may not be used in disregard of the antitrust laws. Finally, . . . when the patent expires, the monopoly created by it expires too, and the right to make the product—including the right to make it in precisely the shape it carried when patented—passes to the public.

Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 229-30 (1964) (footnotes & citations omitted).

113. 21 U.S.C. § 369cc(b) (1988).

114. Thomas, *supra* note 2, at 427.

whatever the traffic will bear and it is a right not limited to the unique regulatory goals sought by Congress in adopting the Orphan Drug Act of only compensating for research and regulatory compliance costs. In the case of patent rights, an unencumbered right of exclusivity to make, use or vend the discovery for a limited time is considered a just trade-off in return for public disclosure of the patented idea in order to promote the primary purpose of the patent laws—the public benefit of the advancement of science and the useful arts by the disclosure of new discoveries and the placing of those ideas in the public domain to stimulate further research and innovation.¹¹⁵ In the case of the Orphan Drug Act there is no such public trade-off because the certificate holder gains an exclusive right to vend whether the idea is patentable or not; and, in the case of patented drugs designated Orphan Drugs, no new benefit is gained by the public in the form of the dedication of new discoveries to the public domain beyond that which is already in the public domain by virtue of the patent system.

As a result, there is growing evidence that the laudable public objectives of the Act in securing the investment and effort necessary to bring drugs to market for diseases effecting a relatively small number are being compromised by excessive profits being made by some certificate holders. It has been noted that:

[T]he Act is over-inclusive. The Act extends the benefits of orphan status to drugs that would be profitable without the incentives. Pharmaceutical companies have occasionally stayed within the letter but not the spirit of the law by taking advantage of the Act's subsidies, producing drugs which would have been justifiable without subsidies despite their small market. Congress currently fears that in some instances, instead of stimulating innovation it has subsidized already profitable pharmaceutical ventures. Congress is therefore threatening to restrict the Act's incentives by eliminating the vital market exclusivity provision.¹¹⁶

115. There is not universal agreement that the trade-off is just. See Tom G. Palmer, *Are Patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects*, 13 HARV. J.L. & PUB. POL'Y 817 *passim* (1990); Evan Mackay, *Economic Incentives In Markets for Information and Innovation*, 13 HARV. J.L. & PUB. POL'Y 867 *passim* (1990).

116. Thomas, *supra* note 2, at 414 (footnotes omitted). Thomas believes that limiting

The over inclusiveness of the Act is a direct result of the Act conferring what are in essence patent rights to charge whatever the traffic will bear. The Act does so in violation of the constitutional limitations upon Congress's limited power to confer patent rights out of the well grounded fear of the Founders that the unconfined grant of market exclusivity rights would result in monopoly profits and barriers to innovation without the conferring of the required public benefits of an otherwise constitutionally limited patent system.

It is apparent that the Orphan Drug Act cannot be analogized to state laws indirectly conferring a property like right as the result of enforcement of unfair competition prohibitions, contract rights or trade secret policies. The Act is a statute aimed at giving producers an incentive to produce by government both creating and conferring a quasi-property right to have others excluded from selling a drug for a period of seven years and is not a statute designed to protect confidential relationships or to protect consumers from deception or other forms of tortious conduct. It is a statute aimed at giving the certificate holder the financial incentives of a patent-like right; a quasi- property right to have others excluded for a limited time from selling a particular drug independent of any tort or contract concerns related to the subject matter. It does so through the licensing powers of the FDA by precluding the FDA, an agency which is otherwise supposed to license drugs found safe and efficacious for sale, from doing so where the drug is one certified as an "orphan drug." The limitation upon the FDA's authority and prevention of competitive entry is not for some health or safety reason or even to protect confidential relationships or the public from fraud, but it is designed to stimulate research and production of drugs by the conferring of an exclusive monopoly right to vend for seven years.¹¹⁷ The Act

the exclusive right would "emasculate" the Act and raise barriers to new product development. *Id.* Her analysis does not consider the question of whether the grant of exclusivity is an unconstitutional grant of patent rights to begin with and whether there are other constitutional means to the end of encouraging development of Orphan Drugs not posing the risks of monopoly pricing and the other anticompetitive consequences the present Act invites.

117. The legislative history of the Act is replete with statements that the primary objective of the seven year exclusive right to vend a designated drug is to provide "an incentive to develop orphan drugs." See, e.g., Orphan Drug Act, H.R. REP. NO. 97-840, 97th Cong., 2d Sess. (1982), reprinted in 128 CONG. REC. 2126 (Feb. 23, 1982) (remarks

converts the FDA from an agency concerned with health and safety issues into a sub-office of the Patent Office and a sub-office without the expertise and responsibilities of the Patent Office to deny grants of an exclusive quasi-property right where the applicant is not an inventor and the subject matter does not represent a discovery advancing the progress of science and the useful arts.

Like the Patent Office, however, the FDA is not permitted to limit the life of exclusivity to a period sufficient to recapture research and regulatory costs in exchange for the conferring of an exclusive right. The period of exclusivity is set by law and bears no necessary relationship to the cost of research or the cost of complying with FDA testing and other requirements. What is conferred is a right of exclusivity bearing no relationship to costs of producing the drug. What is conferred is a patent right within the meaning of the Patent Clause of the Constitution, but one not conforming to the specific limitations upon the power of Congress to create patent rights.

To the extent the Act permits certificate holders who are not inventors to obtain the right from the FDA to have others excluded from vending a drug, whether the drug is patentable or not, the Act clearly violates the constitutional limitation upon granting patent rights to non-inventors.¹¹⁸ To the extent that the Orphan Drug Act permits the withdrawal from the public domain the full use of ideas previously in the public domain, it violates the constitutional limitation upon the creation of patent rights in ideas that are not new discoveries. And, to the extent that the Act both

of Sen. Kassenbaum: The Act "provides financial incentive for the development of orphan drugs in recognition of cost factors which currently discourage their production."); 128 CONG. REC. 25,440 (Sept. 28, 1982) (remarks of Rep. Waxman). No mention is made of limiting the "incentives" provided by the Act to obtaining the Progress of Science and Useful Arts by restricting the exclusive right granted, to new discoveries or to new discoveries by inventors.

The role of the pharmaceutical industry in the adoption of the Act has been described as "first one of disinterest and then one of opportunism." Richardson, *supra* note 1, at 158. The industry lobbying group opposed adoption of legislation to deal with the problem of orphan drugs and sought to use the occasion to seek a relaxation of FDA safety and efficacy regulations for all new drug applications. *Id.* at 158-59.

118. The limitation upon the grant of a patent to a non-inventor is explicit in the Constitution and has been a strictly enforced and consistent requirement of the patent laws. See *supra* note 56 (discussing Constitutional basis for limitations on grant of patent).

deters and fails to promote progress in science and the useful arts by removing ideas from the public domain and restricting free access to and use of subject matter in the public domain, the Act directly conflicts with the basic public purpose behind the constitutional grant of power to Congress to enact patent laws.

III. THE CREATION OF PATENT RIGHTS BY A LAW PASSED
PURSUANT TO THE COMMERCE CLAUSE IS UNCONSTITUTIONAL
WHERE THE ACT CONFLICTS WITH THE LIMITATIONS
OF THE PATENT CLAUSE

The foregoing analysis, demonstrating that the Act creates a patent right within the meaning of the Patent Clause, raises a second fundamental and serious constitutional issue with respect to the Orphan Drug Act: whether Congress may adopt a statute creating patent rights under the commerce power in lieu of exercising its powers under the Patent Clause, where the rights created are not confined in a manner conforming to the limitations found in the Patent Clause. The logic of a negative answer to this issue is that the federal government is a government of limited powers; that Congress can only base its laws upon a specific power delegated to it; that the use of one power to enact a law within a different and limited grant of power may in some circumstances be an unconstitutional exercise of the delegated power; and, that the adoption of a law creating patent rights under the power to regulate commerce rather than the power to create a patent system is an unconstitutional exercise of the commerce power where the rights created do not conform with the limitations of the Patent Clause. If Congress were to use the commerce power through a bill originating in the Senate to, for example, appropriate funds to support an army for four years and impose special taxes to finance the appropriation, the law would be unconstitutional because it would violate the express limitation found in article 1, section 7, clause 1 upon revenue raising bills originating in the House of Representatives and the limitation found in article 1, section 8, clause 12 limiting appropriations to support an army to a two year period. Even if the laws passed under the Commerce Clause generally conformed to the limitations on section 7, clause 1 and section 8, clause 12 of article 1, it should be held that this

misuse of the powers granted Congress holds such potential for abuse that attempts to do so are an unconstitutional exercise of the power granted, as well as an unwise practice for the Congress to adopt.¹¹⁹

A contrary argument must claim that the power to regulate commerce is a plenary power of Congress; one which can be exercised independent of the other clauses granting power to Congress and can be exercised in a way conflicting with the express limitations upon the other powers of Congress. One might argue for example, that the 1937 change in Supreme Court

119. Congress has been engaged in enacting a series of questionable patent-related laws or laws creating patent like rights under the Commerce Clause. For example, the Plant Variety Protection Act, 7 U.S.C. §§ 2231-2583 (1988), grants an exclusive right for seventeen years to the owners of a new sexually reproduced plant. The Act provides a confused and vague explanation of the power exercised as follows:

It is the intent of Congress to provide the indicated protection for new varieties by exercise of any constitutional power needed for that end, so as to afford adequate encouragement for research and for marketing when appropriate to yield the public benefits of new varieties. Constitutional clauses 3 [commerce clause] and 8 [patent clause] of Article 1, section 8 are both relied upon.

7 U.S.C. § 2582 (1988).

The bill which resulted in this statute was not routed through the patent subcommittees of the Judiciary Committees or either house but was considered by the Agriculture Committees of both houses in order to circumvent opposition from Judiciary Committee members to the bill. Irons & Sears, *supra* note 65, at 675 n.91. The resulting Act's standard of invention is constitutionally questionable; delegating administration of a law creating valuable patent rights for agri-business to the Department of Agriculture is of dubious wisdom at best; and, the uncertainty of which power of Congress is being exercised warrant serious reconsideration of the Act by Congress, if not by a court challenge to the validity of the Act because of the ambiguity concerning the level of invention required by the Act.

A similar confusion between the patent power and the Commerce Clause exists with regard to a 1985 amendment to the Orphan Drug Act permitting Orphan Drug status to be extended to patented drugs. See Pub. L. No. 99-91, 99 Stat. 387 (1985) (amending 21 U.S.C. 301, 360 (1988)). The purpose of the amendment was to permit Orphan Drug status to be given patented drugs where patent protection was about to expire. House Energy and Commerce Committee, Orphan Drug Amendments of 1985, H. R. Rep. No. 99-153, reprinted in 1985 U.S.C.C.A.N. 301. The amendment was passed pursuant to the commerce power as an amendment to the Orphan Drug Act and has the effect of expanding the grant of patent protection without the necessary conferring of the constitutional benefit upon the public of some additional disclosure of a discovery promoting progress in science or the useful arts. The amendment is of questionable constitutional validity.

For these and other reasons, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 387 (1984) (codified in scattered sections of Titles 21 & 35 of U.S.C.), apparently passed pursuant to both the Commerce and Patent Clauses, is of questionable constitutionality, as is the Cable Communications Policy Act of 1984. See Pub. L. No. 98-549, 98 Stat. 2279; see also *supra* notes 26, 81.

interpretation of the Constitution permitting a vast expansion of federal power under both the taxing¹²⁰ and commerce powers¹²¹ was a response to the pragmatic need to have a national Congress and Executive branch jurisdictionally competent to handle national problems and free of any significant review by a non-elected, anti-democratic, and nay-saying judicial branch.¹²² The shift in measuring commerce clause authority from a quantitative measurement of the physical movement of commerce and the amount moving to a qualitative test of whether the subject matter regulated was a problem affecting more states than one, might lend credence to a claim that the commerce power includes the power to regulate problems affecting more states than one even where the regulation imposed is within a different and specific limited power of Congress and is imposed in a manner inconsistent with the limitations upon that specific power.¹²³ The obvious consequence of such a holding would be to convert the federal government into one of unlimited powers and write out of the Constitution many of the specific limitations upon the powers of Congress and the President.¹²⁴

120. Compare *United States v. Butler*, 297 U.S. 1 (1936) (holding "processing and floor taxes" unconstitutional) with *Steward Machine Co. v. Davis*, 301 U.S. 548 (1937) (upholding as constitutional social security tax on employees).

121. Compare *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936) (striking down federal laws protecting coal miners as beyond commerce power) with *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937) (upholding NLRA as valid exercise of federal commerce power) and *Wickard v. Filburn*, 317 U.S. 111 (1942) (upholding federal wheat quotas as legitimate exercise of Congress' commerce power).

122. See BRUCE ACKERMAN, *WE THE PEOPLE* 47-49 (1991) suggesting that the 1937 "switch in one saving nine" amounted to a major revision of the Constitution—an amendment of the amending process—when the Court withdrew from extensive review of economic regulation and caused a constitutional transformation building new constitutional foundations for an activist national government. See generally *TRIBE*, *supra* note 58, at 560-86 (discussing evolution of *Lochner* era of finding implied limitations upon power of Congress and its general demise).

123. For an analysis of this type of argument, see *TRIBE*, *supra* note 58, ch.5.

124. It may very well be the case that the language of the Commerce Clause authorizes vast exercises of regulatory authority without the internal language of that clause limiting the commerce power as illustrated in cases like *Wickard v. Filburn*, 317 U.S. 111, 118-29 (1942); *United States v. Darby*, 312 U.S. 100, 123-26 (1941); *Perez v. United States*, 402 U.S. 146, 153-57 (1971); and *Katzenbach v. McClung*, 379 U.S. 294, 303-05 (1964). However, restraints external to the language of the commerce power like the language of other sections and clauses of Article 1 of the Constitution and other articles and amendments to the Constitution should be and are effective constraints.

If, for example, Congress believed that state boundaries were outmoded and prevented effective economic regulation of the country, it could not use the commerce power to eliminate state boundaries and create 10 administrative units to govern local

Research has failed to turn up any cases directly answering this question in the case of the use of the commerce clause to enact laws creating patent rights.¹²⁵ One might argue that the *Trademark Cases*¹²⁶ establish the power to enact laws creating intellectual property-like rights under the Commerce Clause independent of the power to do so under the Patent Clause. A careful reading of the *Trademark Cases* indicates that they establish no such proposition. In those cases, individuals had been indicted under a criminal statute enacted by Congress making it a crime for persons knowingly and with an intent to defraud to make or use a trademark duly recorded and registered with the United States Patent Office. Those charged with violating the statute defended on the ground that the statutes were unconstitutional because it was not within a delegated power of Congress or necessary and proper for the carrying out of a delegated power to enact such a statute. The prosecutors pointed to two powers of Congress, the Patent Clause and the Commerce Clause, as sufficient warrant to uphold the statute.

The Court rejected the claim that the Patent Clause was a sufficient basis for the statute because the essential characteristics of a trademark were not those of inventions or discoveries or the writings of authors. Instead, the Court held that a trademark is a distinctive symbol created by state law and its protection "grows out of its *use*, not its mere adoption."¹²⁷ Consequently, the Court

affairs without running afoul of Article IV, § 4, which provides: "No new States shall be formed or erected within the Jurisdiction of any other State . . . without the consent of the Legislatures of the States concerned" U.S. CONST. art. IV, § 4. By the same token, an even stronger argument can be made that limitations upon powers found within the same article and section of the Constitution as the Commerce Clause cannot be overridden by the exercise of the commerce power without doing great damage to the obvious intent of the Framers and ignoring every rule of construction on the books. For example, if Congress concluded the Supreme Court was undermining its regulatory policy by interpreting statutes with a simple-minded reliance upon naive neo-classical economic analysis, Congress could not use the commerce power to create a super supreme court with jurisdiction over the Supreme Court established by Article III in regulatory matters without violating Article III and the limited power provided by Article I, § 8, cl. 9 vesting power in Congress "to constitute Tribunals *inferior* to the Supreme Court." U.S. CONST. art. I, § 8, cl. 9. (emphasis added).

125. See also MELVIN B. NIMMER, NIMMER ON COPYRIGHT § 1.09 (1991) (stating there are no cases on point of whether Congress may enact copyright legislation under Commerce Clause, although some cases in dictum have "averted to such a possibility").

126. *United States v. Steffens*, 100 U.S. 82 (1879).

127. *Id.* at 94.

concluded it would not be a valid exercise of the power conferred by the Patent Clause to use it to create trademark rights: "While such legislation may be a judicious aid to the common law on the subject of trade-marks and may be within the competency of legislatures whose general powers embrace that class of subjects, we are unable to see any such power in the constitutional provision concerning authors and inventors, and their writings and discoveries."¹²⁸ The implicit decision made is that it is an unconstitutional exercise of the Patent Clause to enact legislation creating property-like rights to exclude all others where the law enacted does not conform to the limitations of the Patent Clause.¹²⁹

With respect to the commerce power, the Court deferred from drawing a general conclusion on the question of whether the statute was a valid exercise of that power out of deference to a co-equal branch of government. Instead of deciding whether Congress could use the Commerce Clause to create patent-like rights, the Court assessed the issue of whether the statute was a valid exercise of the limited power of Congress to regulate that commerce which is interstate or with foreign nations or with the Indian tribes. The court found no such limitation in the statute, nor any allegation in the indictments that the defendants were engaged in misusing registered trademarks in interstate commerce. Consequently, the Court held the statute exceeded the

128. *Id.*

129. Similarly, longstanding proposals to create a form of intellectual property protection for industrial designs, like pending proposals by automobile manufacturers to restrict copying of replacement parts, are clearly unconstitutional. *See, e.g.,* The Design Innovation and Technology Act of 1991, H.R. 1790, 102nd Cong., 1st Sess. (1991); H.R. 3499, 101st Cong., 1st Sess. (1989) (pending legislation to restrict duplication of automobile parts). Such proposals create an exclusive right in a functional design for a period of years and do not rise up to the level of being an "invention" or something contributing to the progress of science and the useful arts. The bill creates an exclusive ten year monopoly not conforming to the requirements of the Patent Clause.

An argument in support of this kind of legislation is that copiers are engaged in a form of "free riding," a simple minded cliché often encountered in antitrust cases that is a surrogate for creating or expanding property rights in ideas or subject matter beyond the limits of the Patent Clause in the name of "fairness" or "efficiency." The *Trademark Cases* and the Patent Clause stand in the way of such legislation, as does the general proposition that copying is often the expression of legitimate competition which should be protected rather than suppressed, particularly through the use of meaningless clichés like "free rider." *See* John J. Flynn, *Antitrust Policy and the Concept of a Competitive Process*, 35 N.Y.L. SCH. L. REV. 893, 907 n.42 (1990).

commerce power and declared the statute unconstitutional.

It is clear that the Court did not address the question of whether Congress could adopt legislation under the Commerce Clause which Congress was precluded from adopting under the Patent Clause, but simply assumed that if the statute was passed pursuant to the Commerce Clause as a means for preventing the misappropriation of state-created trademark rights, the congressional power to do so must be limited to misappropriations occurring in interstate commerce. A more modern approach would hold that the protection of trademarks from misappropriation is not the creation of a patent-like right or a property right because the purpose of trademark protection is the public one of preventing the public from being deceived or misled in the uses made of a trademark. State laws creating such rights and a federal law regulating their use in interstate commerce are not, therefore, the creation of patent-like rights vesting a property right in the holder of the mark, but are consumer protection laws designed to prevent deception. The Lanham Act clearly states as its purpose the "making actionable the deceptive and misleading use of marks" in commerce and the prevention of "fraud and deception" by the use or "reproductions, copies, counterfeits, or colorable imitations of registered marks."¹³⁰ Consequently, the Lanham Act does not create a patent-like interest for mark holders since it only regulates the misuse of trademarks in interstate commerce in ways which deceive consumers.

The only other analogous case which might be relied upon to claim that Congress can use one clause of the Constitution to enact legislation it is expressly authorized by another clause to adopt, is *Heart of Atlanta Motel, Inc. v. United States*.¹³¹ In that case a constitutional challenge was mounted to Title II of the Civil Rights Act prohibiting racial discrimination in public accommodations¹³² by a hotel following the practice of refusing to rent rooms to blacks. One aspect of the challenge claimed that the statute exceeded the commerce powers of the federal government. Congress had passed the Act pursuant to both the Commerce Clause and section 5 of the Fourteenth Amendment authorizing

130. 15 U.S.C. § 1127 (1988).

131. 379 U.S. 241 (1964).

132. *Id.* at 242-43; see 42 U.S.C.A. § 2000 (West 1981 & Supp. 1991).

Congress to pass laws implementing that Amendment.¹³³ Even though there was an express delegation of power to enact the legislation under the Fourteenth Amendment, the Court upheld the law as a valid exercise of the commerce power, stating:

[T]he determinative test of the exercise of power by the Congress under the Commerce Clause is simply whether the activity sought to be regulated is 'commerce which concerns more States than one' and has a real and substantial relation to the national interest.¹³⁴

While one may see an inference in this decision that Congress can regulate anything which involves commerce concerning more states than one, even though it has express power to regulate the conduct under some other clause of the Constitution, it is clear that this case does not address the problem presented by the use of the Commerce Clause to circumvent the limitations of an express power authorizing the law enacted. The Fourteenth Amendment amends the basic document and should be read as expanding the scope of the general commerce power in cases dealing with racial segregation by providing an expanded basis for regulating the practice, particularly to limit state action authorizing or requiring racial segregation. As such, it is consistent with and expands the power granted Congress to regulate commerce by proscribing racial discrimination by state action as well as part of Congress' power to regulate private economic conduct involving commerce and is not a limitation upon or inconsistent with the commerce power which it amends.

Unlike the Fourteenth Amendment authorization for Congress to enact laws implementing the Amendment and expanding the basic powers of Congress found in Article 1, the Patent Clause is a carefully crafted clause limiting the scope of all the powers granted by Article 1, section 8 in light of prior experience with grants of unlimited monopoly power by government. As noted earlier, the limitations upon the power to enact patent legislation include a basic understanding that the purpose

133. U.S. CONST., amend. XIV, § 5 provides: "The Congress shall have power to enforce, by appropriate legislation, the provisions of this article."

134. *Atlanta Motel*, 379 U.S. at 356.

of patent legislation must be the public one of advancing science and the useful arts by the disclosure of new inventions by inventors in exchange for a right to exclude others for a limited time. The public purpose of achieving disclosure is primary and the private right to exclude is subsidiary and tolerated to the extent necessary to induce the disclosure of new and inventive ideas. The Orphan Drug Act requires no such exchange, whether the drug is patented, patentable or not patentable; whether the drug is in the public domain or not; and, whether the applicant is an inventor or not. Moreover, the right of excluding others is made primary in order to achieve the secondary objective of inducing research and the expense of complying with FDA regulation to secure the vending of drugs for orphan diseases—not to obtain disclosure of a new discovery.

To permit Congress to escape the limitations of the Patent Clause by relying upon the Commerce Clause to enact legislation creating patent rights undermines the basic policy of the Patent Clause, makes the Patent Clause a dead letter as a constraint upon the power of Congress to create patent rights, and violates the canon of constitutional and statutory construction *expressio unius est exclusio alterius*.¹³⁵ It is a basic rule of construction recognized ever since *Marbury v. Madison* held that the Congress was without power to use the delegation of power to Congress to define the appellate jurisdiction of inferior courts to amend the express delegation of limited original jurisdiction to the Supreme Court.¹³⁶ In *Marbury*, Chief Justice Marshall wrote:

If it had been intended to leave it in the discretion of the legislature, to apportion the judicial power between the supreme and inferior courts, according to the will of that body, it would certainly have been useless to have proceeded further than to have defined the judicial power, and the tribunals in which it should be vested. The subsequent part of the section is mere surplusage—is entirely without meaning, if such is to be the construction. If congress remains at liberty to give this court appellate jurisdiction, where the constitution has declared their jurisdiction shall be original; and original jurisdiction where the constitution has declared it shall be

135. "Expression of one thing is the exclusion of another."

136. 5 U.S. (1 Cranch) 137 (1803).

appellate; the distribution of jurisdiction, made in the constitution, is form without substance.

It cannot be presumed, that any clause in the constitution is intended to be without effect; and therefore, such a construction is inadmissible, unless the words require it.¹³⁷

The explanation for the paucity of cases on the question of whether Congress may use one power to circumvent limits of another is that Congress has usually been careful about doing so ever since *Marbury v. Madison*. When complex issues of intellectual property protection are raised, Congress has usually—but not always—shown extreme care in sorting out the constitutional basis for its actions. A recent example is the Semiconductor Chip Protection Act of 1984,¹³⁸ a carefully crafted statute designed to deal with the difficult issues surrounding the protection of new forms of complex technology.¹³⁹ Congress demonstrated extreme

137. *Id.* at 174. In upholding the authority of the Court to declare the law unconstitutional, Marshall went on to observe:

The powers of the legislature are defined and limited; and that those limits may not be mistaken or forgotten, the constitution is written. To what purpose are powers limited, and to what purpose is that limitation committed to writing, if these limits may, at any time, be passed by those intended to be restrained? The distinction between a government with limited and unlimited powers is abolished, if those limits do not confine the persons on whom they are imposed, and if acts prohibited and acts allowed, are of equal obligation. It is a proposition too plain to be contested, that the constitution controls any legislative act repugnant to it; or that the legislature may alter the constitution by an ordinary act.

Between these alternatives, there is no middle ground. The constitution is either a superior paramount law, unchangeable by ordinary means, or it is on a level with ordinary legislative acts, and, like other acts, is alterable when the legislature shall please to alter it. If the former part of the alternative be true, then a legislative act, contrary to the constitution, is not law; if the latter part be true, then written constitutions are absurd attempts, on the part of the people, to limit a power, in its own nature, illimitable.

Certainly, all those who have framed written constitutions contemplate them as forming the fundamental and paramount law of the nation, and consequently, the theory of every such government must be, that an act of the legislature, repugnant to the constitution, is void.

Id. at 176.

138. 17 U.S.C. §§ 901-14 (1988 & Supp. II 1990).

139. Similar problems exist regarding other new technologies like the protection of computer software even though the Court has upheld patentability where the invention claimed covers a process which is broader than the simple reliance upon or implementation of an algorithm. See *Diamond v. Diehr*, 450 U.S. 175 (1981). See generally Daniel G. Feder, Comment, *Computer Software: Hybrid Technology Demanding A Unique*

care in exercising its power under the Patent Clause to enact copyright legislation by limiting the protection to "mask works," or the things which embody the design of the semiconductor chip and not the chip itself. Doing so avoided the difficulty of violating a fundamental tenet of copyright law that a copyright does not protect useful or utilitarian articles standing alone, but can only protect the nonfunctional aspects of their design, and the further difficulty of whether the chip itself would constitute a writing.¹⁴⁰ Congress was also careful to use its commerce power to protect against the piracy of mask works in or affecting commerce¹⁴¹ in the event a mask work was found not to be a writing.¹⁴² This careful specification of the powers being exercised and the limitation of the use of the power in conformity with the restrictions placed upon the power by the Constitution suggest that Congress is well aware of the constitutional difficulties with passing a law creating patent rights under the Commerce Clause or in attempting to use the general commerce power to circumvent the limitations of the patent power when these issues are raised in the course of the legislative process.¹⁴³

Unlike the ambiguous use of multiple powers of Congress in the *Trademark Cases* and reliance upon an amendment to the basic powers of Congress in the *Heart of Atlanta Motel* case, adoption of the Orphan Drug Act was clearly done pursuant to the power to regulate commerce and not pursuant to the Patent Clause or a subsequent amendment to the Constitution. Moreover, the circumstances of the Act's adoption clearly involve an instance

Combination of Copyright and Patent Protection, 59 UMKC L. REV. 1037, 1059-74 (1991). Similar complex issues are arising in the patentability of the product of biotechnology and genetics research. See Kevin W. O'Connor, *Patenting Animals and Other Living Things*, 65 S. CAL. L. REV. 597 (1991).

140. See generally Robert W. Kastenmeier & Michael J. Remington, *The Semiconductor Chip Protection Act of 1984: A Swamp or Firm Ground*, 70 MINN. L. REV. 417 *passim* (1985). For a thoughtful exploration of the practical implications of the Act, see Leo J. Raskind, *Reverse Engineering, Unfair Competition, and Fair Use*, 70 MINN. L. REV. 385, 390-415 (1985).

141. 17 U.S.C. § 910 (1988).

142. See Kastenmeier & Remington, *supra* note 140, at 420-21.

143. Issues which should be raised with regard to obviously questionable proposals like the pending Design Innovation and Technology Act of 1991, H.R. 179, 102d Cong., 1st Sess. (1991), a bill proposing to create 10 years of exclusive protection for "original designs of useful products" and not conforming to the limitations of the Patent Clause. See *supra* note 129 (discussing Design Innovation and Technology Act and its Patent Clause limitations).

where the power granted Congress to confer patent rights—the Patent Clause—and being circumvented by reliance on the Commerce Clause to pass the Act. As noted above, the Act violates the express limitations found in the Patent Clause because: The grant of exclusivity conferred by the FDA under the Orphan Drug Act is not limited to inventors; the grant of exclusivity is not for the progress of science and the useful arts; the grant of exclusivity need not involve the disclosure of anything not already in the public domain; and, the grant of exclusivity need not rise up to the level of being a new discovery in order to receive a monopoly seven year right to be the exclusive vendor of the designated drug.

Consequently, there is a serious and substantial likelihood that a court will hold that in the case of powers granted to Congress under article 1, section 8, clause 8 of the Constitution, the Congress may not use one power to enact legislation specifically authorized by another where there is a potential that such a practice will result in violating restrictions on the use of the specific granted power. This is the underlying holding of the Supreme Court in *Railway Labor Executives Ass'n v. Gibbons*,¹⁴⁴ where the Court struck down a special bankruptcy statute because it lacked the "uniformity" required of bankruptcy laws found in the grant of the power to enact bankruptcy laws in article I, section 8, clause 4 of the Constitution.¹⁴⁵ The Court held:

We do not understand either appellant or the United States to argue that Congress may enact bankruptcy laws pursuant to its power under the Commerce Clause. Unlike the Commerce Clause, the Bankruptcy Clause itself contains an affirmative limitation or restriction upon Congress' power: bankruptcy laws must be uniform throughout the United States. Such uniformity in the applicability of legislation is

144. 455 U.S. 457 (1982).

145. *Id.* at 468-73. A preliminary issue in the case was whether the sections of the statute in question, labor protection provisions for employees laid off as the result of the bankruptcy of the Rock Island Railroad, were an exercise of the bankruptcy power or the commerce power. *Id.* at 465-68. Because the Act provided for the sums to be paid displaced employees to come from the bankrupt estate and gave priority to employee claims, the Court held the Act to be an exercise of the bankruptcy power. *Id.* Similarly, in the case of the Orphan Drug Act, it must first be determined whether the seven years market exclusivity right is the creation of a "patent right." The prior analysis of this Article clearly establishes that the seven year right of exclusivity conferred by the Act is a "patent right."

not required by the Commerce Clause. Thus, if we were to hold that Congress had the power to enact non-uniform bankruptcy laws pursuant to the Commerce Clause, we would eradicate from the Constitution a limitation on the power of Congress to enact bankruptcy laws.¹⁴⁶

This dicta reiterates the policy Justice Marshall enunciated in *Marbury v. Madison*: Congress may not enact a law under one clause of the Constitution where that law falls within another power of Congress and where the other power of Congress contains express limitations not found in the power being exercised. This is clearly the case with the Orphan Drug Act since the right created is a patent right permitting unregulated returns during the period of exclusivity and it is not carefully crafted to limit the award granted to the incentives found necessary: recovery of the research and FDA application costs plus a reasonable profit.¹⁴⁷ The exclusive seven year right granted is an unlimited one, a right to charge what the traffic will bear with no corresponding conferring of a public benefit of advancing the progress of science and the useful arts by the disclosure of a new invention and no necessary relation to reducing the barriers to orphan drug development. The Act creates a right which can be and is often conferred upon non-inventors. What Congress is specifically prohibited from doing by one clause of the Constitution it should not, and likely will not, be permitted to do by another and more general grant of power.

It might also be a plausible argument to claim that even if the Act did conform to the limitations of the Patent Clause, it should be declared an unconstitutional exercise of the Commerce

146. *Gibbons*, 455 U.S. at 468 -69 (citations omitted).

147. The Orphan Drug Act's other incentives are designed to aid in recoupment of development costs. They appear to be valid exercises of the taxing and spending powers. They include a streamlining of FDA approval process by permitting a request of the FDA for written recommendations for clinical and non-clinical tests necessary for approval (21 U.S.C. § 360aa(a) (1988)); tax breaks for expenses related to orphan drug development (26 U.S.C. §§ 44H, 280C (1988)); FDA funding for assisting in the clinical testing necessary for approval of an orphan drug (21 U.S.C. § 360ee(a) (1988)); and, the creation of the Orphan Products Board to coordinate public and private development efforts (42 U.S.C. § 236 (1988)). Adding an unregulated and exclusive seven year right to have all other sellers excluded, with the obvious invitation to engage in monopoly pricing, would appear to be more than frosting on the cake. It is the grant of a right unrelated to the specific limitations hindering orphan drug development—research costs, development costs, and the costs of complying with FDA regulations compensated for by the other incentives provided by the Act.

Clause to use the power to enact laws within the express grant of power conferred by the Patent Clause. A reasoned construction of the Constitution, one consistent with rules of construction and *Marbury*, the nature of delegated powers, and the obvious intent of the Framers, is that a specific grant of power ought not be subsumed under a general grant of power. To do so would violate the obvious intent of the Framers to treat the matters as distinct and hold the potential for too much mischief like leaving the power being exercised vague and ambiguous. Such a practice, one apparently followed in the *Trademark Cases*, the *Railway Labor* case, and statutes like The Plant Variety Protection Act,¹⁴⁸ would require the courts to guess which power Congress intended to exercise and then to sort out those circumstances in which the specific grant of power ought and ought not be subsumed under the general grant of power. Moreover, such a construction would violate the basic principle that the federal government is a government of limited powers and can only act pursuant to the specific powers granted. By holding Congress must act only pursuant to a specific power which Congress initially selects and that it must be the power authorizing the exercise of the power being exercised, courts would place the responsibility on Congress to identify the power it has invoked and insure that Congress considers carefully the legitimacy of the law it proposes to enact. Doing so would also insure that the proposal is subject to scrutiny by the appropriate committees of Congress where issues of constitutional limitations upon the exercise of the power would more likely be carefully considered.

This is a responsibility Congress has generally assumed and usually exercised by specifically designating the power it is relying upon when enacting a law rather than leaving it to the courts to sort out later whether Congress exercised a power granted to it, which one did it exercise, and whether the exercise is an appropriate use of the power the courts guess Congress relied upon. It is for these reasons that it is at least a plausible argument that a court could find the use of the commerce power to enact a law which creates rights within the Patent Clause is unconstitutional and strike the law down even if the law did conform generally with the more restrictive limitations of the Patent Clause. The

148. See *supra* note 119 (discussing Plant Variety Protection Act).

argument is conclusive in light of *Marbury* and the *Railway Labor Executives* case, where the law adopted pursuant to the commerce clause creating patent rights does so in a manner which conflicts with the inherent limitations upon the powers of Congress to enact patent laws imposed by the Patent Clause, as is clearly the case with the Orphan Drug Act.

IV. CONCLUSION

Congress must give careful consideration to the nature of the exclusive right that is created by the Orphan Drug Act and restrict the Act in a way which links and limits the right of exclusivity to the incentives Congress recognized as necessary to induce research and recover the expense of complying with FDA registration of new drugs. The incentive currently authorized is an exclusive and unregulated one for a seven year period and is resulting in monopoly pricing for several drugs; pricing unrelated to the costs of research and complying with FDA registration and testing requirements. It has all the characteristics of a patent right and not that of a narrowly drawn subsidy to induce the bringing of Orphan Drugs to market in light of and limited by the costs of research and compliance with regulatory requirements to insure the safety and efficacy of the drug. Existing subsidies for research and clinical testing go far in reducing entry barriers to the development and marketing of drugs for rare diseases. Adding a patent right of market exclusivity for seven years allows those obtaining the right to go well beyond recouping research, development, and regulatory compliance costs. When coupled with the possibility of obtaining independent patent protection for truly new discoveries or an exclusive license to government developed or financed patent rights, the shower of public benefits granted drug manufacturers becomes an unnecessary and excessive embarrassment of riches.

Few would contest the merit of government seeking ways to stimulate research and development of drugs to treat rare or uncommon diseases where the market incentives for private firms to do so are inadequate. But the methods by which government chooses to do so are subject to constitutional constraints as well as

common sense ones; constraints which are based upon a history and experience with abuses of methods barred by limitations expressly placed upon the powers of Congress to create exclusive and unregulated monopoly rights. Granting an exclusive seven year unregulated right to vend a product in order to provide an incentive to research and develop orphan drugs, violates the long history and experience with governmental grants of monopolies and the specific limitations placed upon the power to do so by the Patent Clause of the Constitution. Had Congress considered or been confronted with these limitations when it originally adopted the Act, it is likely that other and constitutional means would have been adopted to achieve the end and avoid the predictable abuses now plaguing the Act.

The present means of conferring a seven year exclusive and unregulated monopoly over vending a drug is a form of discredited 1980s trickle down economic theory—that the beneficiary of the monopoly will be benevolent and exercise the monopoly in a non-exploitative manner for the benefit of victims of rare diseases. But the long history of unregulated monopolies should have at least taught us not to trust the benevolence of a monopolist,¹⁴⁹ particularly one granted an unregulated monopoly by government—a monopoly enforced by government. There is now considerable evidence that the exclusive and unregulated monopolies conferred by the Orphan Drug Act are being abused, particularly by

149. Adam Smith's famous statement in *The Wealth of Nations*: "It is not from the benevolence of the butcher, the brewer, or the baker that we expect our dinner, but from their regard to their own interest" is a recognition that self-interest is the most powerful incentive to inducing someone to bring goods to the market. ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS 7 (Great Books 1952). Smith also recognized that self interest causes great injury to the common good in the case of the grant of a monopoly because it results "upon every occasion [in] the highest price which can be got," *id.* at 26, and that "[m]onopoly . . . is a great enemy to good management . . ." *Id.* at 63. Smith saw a justification for a narrow and limited grant of monopolies for a short time by the sovereign for establishing a new trade in "some remote and barbarous nation" and for a limited monopoly for a short time for the inventor of "a new machine" and for a "new book to its author." *Id.* at 329. The grant of monopolies otherwise results in

all other subjects of the state [being] taxed very absurdly in two different ways: first, by the high price of goods, which, in the case of a free trade they could buy much cheaper; and, secondly by their total exclusion from a branch of business which is might be both convenient and profitable for many of them to carry on.

Id. at 329.

monopoly pricing practices exploiting the most vulnerable among us and the intended beneficiaries of the Act—victims of relatively rare diseases. Excluding competition in providing orphan drugs not only results in unjustified monopoly pricing, but likely deprives the intended beneficiaries from further innovation in providing the drug, improving the drug and its manufacture and in expanding research into additional and different treatment of the disease. Monopoly pricing imposes a tax on the victims of rare diseases to achieve what should be a public obligation of society to provide safe and efficacious drugs to treat rare illnesses as well as common ones.

Congress must therefore, reassess the unconstitutional grant of exclusivity by, for example, providing for termination of exclusivity once research and other costs plus a reasonable profit are recovered within the seven year period or once a certain level of return is realized from sales of the drug.¹⁵⁰ Such steps would tend to shift the right granted by the Act from a private patent-like exclusive right to sell to one akin to the public right of exclusivity given natural monopolies and subjected to affirmative rate regulation. In effect, it would be rate regulation in the form of a crude rate cap. While these forms of limitations upon the scope of the monopoly right granted may tend to shift the right granted from out of the realm of a patent right, the Act will still remain vulnerable both to a growing public concern over the monopoly prices charged for some orphan drugs and a constitutional challenge to the ability of Congress to enact a law which goes beyond granting a perhaps legitimate regulatory incentive and creates what are in essence exclusive property rights without complying with the limitations of the Patent Clause. Although still subject to constitutional question, such proposals are at least a step in the right direction.

Another option is to make the subsidy for research on orphan illnesses direct, rather than indirect, by affirmatively expanding

150. See S. 2060, 102nd Cong., 1st Sess. (1991) (proposing to open consideration of new applications for sale of the designated drug once cumulative net sales reach \$150 million and to terminate exclusivity and authorize competing sales where cumulative net sales reach \$200 million). H.R. 5421, 101st Cong., 2d Sess. (1990), proposed the imposition of an excess profits tax once the gross revenues from sales during the taxable year reached 125% of the sum of the cost of producing the drug sold during the year and marketing costs.

funding out of general revenues for research on specific rare illnesses. Such an approach avoids the difficulty of delegating an unlimited taxing power for seven years to the holder of an orphan drug license; a taxing power which can be unfairly imposed on those suffering the illness, and a power which can be used to realize returns far in excess of the research and licensing costs incurred without any guarantee that the monopoly profits realized will be wisely re-invested in further research or be re-invested at all. This approach may suffer however from the on-going abuse of granting exclusive licenses on government funded research to private parties, a method of circumventing the general policy prohibiting the government grant of an exclusive monopoly right without an additional disclosure of a new discovery by the beneficiary of the grant.

An option avoiding the limitations of both placing a crude rate cap on profits and expanding government control over research funding might be to mandate compulsory licensing of all exclusive rights over drugs—those conferred by patent law, government licensing of government owned patents or statutes like the Orphan Drug Act conferring an unconstitutional patent right. Drug prices in other nations are lower than in the United States because of the availability of compulsory licensing.¹⁵¹ It has even been suggested that the problem of excessive drug prices for patented drugs generally be dealt with by invoking the power of the federal government to condemn existing patent rights accompanied by payment of reasonable compensation under an old law authorizing the manufacture of a patented product by others if needed to protect the welfare of the country.¹⁵² These types of remedies may ameliorate excessive pricing for patented drugs, but do not resolve the deeper question raised by the Orphan Drug Act—the constitutional disability of Congress to create such a right of exclusivity to begin with.

A final option Congress should consider for all drugs and appliances in need of FDA approval in order to market the drugs or appliances as well as Orphan Drugs,¹⁵³ is to reform the

151. See Desrosiers, *supra* note 2, at 144-45.

152. 28 U.S.C. § 1498; see also Desrosiers, *supra* note 2, at 145 (discussing federal condemnation of patent rights in drugs).

153. Regulation of the medical appliances market appears to be in need of a drastic overhaul. It has been essentially deregulated by the failure of the FDA to implement its

economic basis upon which clinical testing is conducted—usually the most expensive factor in bringing safe and efficacious drugs and appliances to market. Congress should consider placing responsibility for conducting clinical testing in the hands of the FDA directly by legislation shifting responsibility for arranging clinical testing from manufacturers to the FDA. Financing the cost of this shift of responsibility could be done by imposing a manufacturing or wholesale tax on all prescription drugs and devices requiring FDA approval in lieu of manufacturers including clinical testing costs in the price charged consumers for the drug or appliance. Revenues from the tax could then be used by the FDA to engage private concerns and individuals in conducting the clinical trials, under a regime of competitive bidding pursuant to FDA specifications. Such a change would not only remove the most significant entry barrier to research and development of drugs and appliances for all diseases and introduce competition into the process for securing clinical testing services for all drugs and appliances, but it would also give the FDA direct control over what have become significant abuses of the present system of private financing and responsibility for the honesty and integrity of clinical trials. Rather than reporting the results of clinical trials to the FDA through the filter of the applicant seeking approval for the drug or appliance, those engaged in clinical testing would be directly responsible to the FDA. Failure to fully disclose the results of clinical trials would be much less likely to happen and could be more directly controlled and taken account of by the FDA.

This last reform, coupled with tax and direct research incentives and the abolition of the unconstitutional seven year exclusivity right granted by the present Act, would appear to be the most direct solution to the present legal and practical difficulties with the Act. Minimizing the practical economic barriers to orphan drug research, development and testing opens the way to competition defining the scope of private effort in developing drugs with a minimal market potential, as well as drugs with much larger markets potential. The public remedy is far more accurately

regulatory authority and the failure of Congress to appropriate sufficient funds to implement effective regulation. The results are a predictable increase in defective or dangerous devices on the market and serious injuries and death for patients subjected to their use. See Bruce Ingersoll, *Health Risk: Amid Lax Regulation, Medical Devices Flood A Vulnerable Market*, WALL ST. J., March 24, 1992, at A1.

linked to the barriers creating dis-incentives for Orphan Drugs, instead of the present system of apparently vast reward for minimal risk in too many instances.

Short of these kinds of reforms, the present grant of market exclusivity by the Orphan Drug Act is seriously vulnerable to constitutional challenge because: (1) The Act creates patent rights without conforming to the constitutional limitations upon the power of Congress to do so; and (2) Congress has exercised the commerce power to create patent rights in a manner not conforming to the limitations of the Patent Clause when it adopted the Act and the FDA has been engaged in conferring what are patent rights in its administration of the Act. If Congress and the President truly care about developing safe and efficacious drugs to treat rare diseases, rather than protecting opportunities for unregulated monopoly profits of drug producers, they must find a constitutional method for stimulating research and development of orphan drugs before the courts are compelled to find the exclusive marketing right of the Orphan Drug Act an unconstitutional exercise by the Congress and the FDA of the power conferred by the Patent Clause of the Constitution.

